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No. 95-1323

In The

Supreme Court of the United States

October Term, 1995

BARBARA MITCHELL and GREGORY MITCHELL,

Petitioners,

v.

COLLAGEN CORPORATION,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Do the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 360c et seq., preempt state tort law claims to recover for injuries caused by a PMA-approved Class III medical device?

2. Does a defendant's motion for summary judgment, which alleges as its sole ground the legal issue of federal preemption, suffice under *Celotex* to put at issue the underlying factual merits of the plaintiff's claims?

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Barbara and Gregory Mitchell respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit in this case.

On January 19, 1996, this Court granted the petitions for writ of certiorari filed by both sides in *Lohr v. Medtronic, Inc.*, No. 95-886 and No. 95-754. The issues presented in *Lohr* are very similar to those presented in this Petition regarding preemption of state tort law claims under the Medical Device Amendments of 1976 ("MDA"). However, this case involves a Class III medical device which has itself been through the MDA pre-marketing approval ("PMA") process. *Lohr* involves a device marketed under Sec. 510(k) as "substantially equivalent" to a previously marketed Class III medical device[1]

Disposition of the underlying preemption issue in *Lohr* may or may not control disposition of the preemption issue herein, depending on whether the Court strikes a distinction between "substantially equivalent" and PMA-approved Class III devices for purposes of MDA preemption. Judicial consistency and efficiency would suggest the consolidation of this cause with *Lohr*; in the alternative, any controlling difference between the two

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[1] Likewise, the pending Petitions for Writ of Certiorari in *Duvall v. Bristol-Myers-Squibb*, No. 1010, *English v. Mentor Corp.*, No. 95-1034, and *Mentor Corporation v. Feldt*, No. 1214, involve MDA preemption of claims regarding Sec. 510(k) "substantially-equivalent" medical devices. *Mitchell* herein and *Talbott v. C.R. Bard* (filed 2/16/96) are the only currently pending petitions involving preemption of a PMA-approved Class III medical device.

types of regulatory devices would require granting writ in *Mitchell* independently of *Lohr*.

The Mitchells' Petition is complementary, but not identical, to *Lohr*, and presents the Court with an opportunity to address and resolve a wider spectrum of the MDA-preemption question than is presented by *Lohr* alone.

OPINIONS BELOW

The opinion of the Court of Appeals for the Seventh Circuit, App. at 1-38, is reported at 67 F.3d 1268. The Order of the Court of Appeals overruling Petitioners' petition for rehearing appears at App. 39. The opinion of the United States District Court for the Northern District of Indiana, Hammond Division, is reported at 870 F.Supp. 885. App. 40-69.

JURISDICTION

The judgment of the Court of Appeals was entered on October 2, 1995. App. at 1. A timely petition for rehearing was filed by the Mitchells on October 16, 1995, which was denied on November 22, 1995. App. at 39. This Court has jurisdiction under 28 U.S.C. Sec. 1254(1).

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. Sec. 360k provides:

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt Requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter, which would be applicable to the device if an exemption were not in effect under this subdivision; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. Sec. 360h(d) provides:

Effect on other liability. Compliance with an order under this section shall not relieve any person of liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 C.F.R. Sec. 808.1(d) provides in pertinent part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or

local requirements that are not regarded as preempted by section 521 of the act:

> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranties of fitness)), or to unfair practices in which the requirements are not limited to devices . . .

STATEMENT OF THE CASE

The Mitchells brought state law products liability, negligence, warranty, fraud, misbranding, adulterated device and mislabeling claims against Collagen Corporation, seeking damages for injuries caused to Barbara Mitchell by injections of Collagen Corporation's Class III medical device, Zyderm. The United States district court granted summary judgment in favor of Collagen Corporation, holding that the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act preempted all of the Mitchell's claims. The Court of Appeals for the Seventh Circuit affirmed, holding that the MDA preempted the Mitchell's claims for strict liability, negligence, mislabeling, misbranding, and fraud on the FDA, but not for breach of express warranty. The court's opinion is unclear as to whether it preempted claims for adulterated device and fraud/misrepresentation in device promotionals and advertisements. The court of appeals affirmed by holding that Petitioners, regardless

of preemption, had not proved the factual merits of their underlying claims as to such fraud, misrepresentation, adulteration and express warranty claims.

The basic structure of the federal medical device laws is described in Part A below. Part B considers the underlying facts and proceedings before the district court, and Part C sets out the main holdings of the court of appeals.

A. The Basic Structure of the Medical Device Amendments of 1976

Prior to enactment of the MDA in 1976, medical devices were substantially unregulated; the FDA was without specific authority to prevent or regulate the marketing of new devices. In 1976 Congress enacted the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. Sec. 360c et seq., which gave the FDA authority to regulate introduction of medical devices into the market. The MDA was enacted largely in response to the medical fiasco of the Dalkon Shield IUD, an unregulated device with a faulty design which caused serious injury to thousands of women during the 1970s. H.R. Rep. No. 853, 94th Cong., 2d Sess. at 8, 12 (1976). The purpose of the MDA was to increase consumer protection by preventing the marketing of dangerous devices, and to assure the marketing of only reasonably safe and effective devices. *Id.* at 1-2.

Under the MDA, Class III devices such as Collagen Corporation's Zyderm pose a potentially unreasonable risk of harm to patients. 21 U.S.C. Sec. 360c(a)(1)(C). Class III devices are subject to premarket application approval ("PMA"). The FDA may grant pre-market

approval if it finds that there is "reasonable assurance" that the device is safe and effective. 21 U.S.C. Sec. 360e(d)(2). While the MDA required the FDA to promulgate regulations to effectuate the MDA, these regulations were not promulgated and put into effect until 1986.

A significant number of Class III medical devices, however, are allowed on the market because they are "substantially equivalent" to already-approved devices. Section 510(k) of the MDA authorizes these devices to be marketed without PMA-approval. The *Lohr* and *Duvall* petitions set forth an excellent discussion of Sec. 510(k) considerations, which need not be repeated here.

In 1981, the FDA approved the PMA for Collagen Corporation's medical device, Zyderm. Zyderm, therefore, is a PMA-approved Class III medical device.

B. Facts and District Court Proceedings

Barbara Mitchell began receiving facial injections of Zyderm in 1988. Zyderm is cow tissue manufactured and marketed by Collagen Corporation as a medical "treatment" for facial wrinkles. Following her injections, Mrs. Mitchell developed serious medical complications from the device, which have culminated in a life-debilitating autoimmune-disease disorder for which there is no cure.

In January of 1993, the Mitchells filed suit against Collagen Corporation, claiming strict liability for defective design, defective manufacturing and failure to warn; negligence in design, manufacture, marketing, testing, and sale; breach of warranties, fraud and misrepresentations; mislabeling, misbranding and adulterated device.

As part of these allegations, the Mitchells claimed that Collagen Corporation failed to monitor adverse reactions and report them to the FDA.

Collagen Corporation filed for summary judgment, alleging that Sec. 360k(a) of the Medical Device Amendments of 1976 preempted all of the Mitchells' state law claims. The district court granted summary judgment, agreeing that the MDA preempted all of the Mitchell's causes of action. App. at 66-69.

C. Court of Appeals Decision

The Court of Appeals for the Seventh Circuit affirmed the district court's granting of summary judgment, but held that express warranty claims are not preempted by the MDA. It is unclear as to whether the Seventh Circuit also held that fraud and adulteration claims in general are not preempted by the MDA, as the appellate court ruled that the Mitchells had not established the underlying factual validity of such claims.

As to preemption, the court of appeals specifically declined to apply 21 U.S.C. Sec. 808.1(d), which states that Sec. 360k(a) does not preempt state laws of "general applicability."

Moreover, the court of appeals ruled that the entire PMA-approval process is a specific requirement applicable to a particular device, such that the Mitchell's strict liability, negligence and fraud claims were preempted.

REASONS FOR GRANTING THE PETITION

I. THE COURT HAS GRANTED CERTIORARI IN *LOHR*, WHICH PREEMPTION ISSUE PRESENTS A COMPLEMENTARY BUT ANALOGOUS QUESTION TO THIS PETITION.

On January 19, 1996, the Court granted the petitions for writ of certiorari filed by both sides in *Lohr v. Medtronic*, No. 95-886 and No. 95-754. The Question presented by *Lohr* is essentially the same as that presented here by the Mitchells: whether the MDA preempts state law claims to recover for injuries caused by a Class III medical device. The Court's disposition of *Lohr* will substantially impact disposition of the Mitchell's claims, but it may not necessarily answer the *entire* MDA-preemption question. While Sec. 360k(a) applies to all Class III medical devices, the MDA recognizes more than one way to obtain marketing-approval for a Class III device: a device may be PMA-approved (premarket application); it may be approved for marketing as a Sec. 510(k) "substantially equivalent" device, or it may be allowed as a pre-existing or "grandfathered" device under Sec. 510(k).

Of the petitions known to the Mitchells as currently pending before this Court on the issue of MDA preemption, only this Petition and that of *Talbott v. C.R. Bard* involve *a PMA-approved Class III medical device;* the remainder involve "substantially equivalent" Class III devices under Sec. 510(k) of the MDA. Some courts have debated the effective distinction between PMA-approved devices and Sec. 510(k) "grandfathered" or "substantially

equivalent" devices.[2] Taken together, the granting of this Petition and the petitions in *Lohr* will ideally promote judicial economy and consistency as to the entire regulatory question of MDA preemption of state law claims regarding Class III devices.

II. THE SEVENTH CIRCUIT'S PREEMPTION DECISION IRRECONCILABLY CONFLICTS WITH OTHER CIRCUIT DECISIONS.

The court of appeals held that the Mitchell's claims for strict liability, negligence, mislabeling, adulteration, misbranding, fraud and misrepresentation allegations are preempted by Sec. 360k(a) of the MDA, but that a breach of express warranty claim would not be preempted. These rulings conflict with decisions of other courts of appeal, particularly with *Kennedy v. Collagen Corporation*, 67 F.3d 1453 (9th Cir. 1995). *Kennedy* and *Mitchell* create a direct irreconcilable conflict, with the Ninth Circuit in *Kennedy* holding that the MDA does not preempt state law claims of general applicability regarding Class III devices, and the Seventh Circuit in *Mitchell* holding that substantially all state law claims are preempted.

In declining to find preemption under the MDA, *Kennedy* held that two FDA regulations clearly spell out

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[2] *See*, e.g., *Reeves v. Acromed*, 44 F.3d 300 (5th Cir. 1995). This issue is the subject of the petitions in *Lohr*, *Duvall*, *English*, and *Feldt*, *supra* at fn. 1. There are also reported decisions involving IDE (investigational device exemption) devices, which are subject to precise requirements and provisions incongruous to ordinary Class III devices, and will not be discussed here.

the scope and extent of preemption under Sec. 360k(a). Under 21 C.F.R. Sec. 808.1(d), Sec. 360k(a) preempts state or local requirements only when it "has established *specific* counterpart regulations or there are other specific requirements applicable to a *particular* device under the act," and that Sec. 360k(a) likewise does not preempt "State or local requirements of *general applicability* where the purpose of the requirement relates either to other products in addition to [medical] devices." As stated in *Kennedy*,

> [I]f a state common law requirement is not specifically directed at medical devices, but affects such devices in the same manner as it affects all other products, a claim based on that state law requirement is not preempted. Accordingly, generally applicable state common law, including tort law, is not preempted by Sec. 360k(a).

Kennedy at 1462 (Reinhardt, J., concurring). The court of appeals in *Mitchell*, of course, reached its preemptive conclusion by ignoring these two FDA regulations.

Other courts of appeal, in addressing the scope of an MDA preemption, have littered the judicial picture with inconsistent and conflicting opinions:

First Circuit:	*King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993): MDA preempts all state law claims; *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995): MDA preempts all tort claims, even proven criminal fraud on the FDA); *Mendes v. Medtronic, Inc.*, 18

F.3d 13 (1st Cir. 1994): (MDA preempts all state claims).

Third Circuit: *English v. Mentor*, 67 F.3d 477 (3d Cir. 1995): MDA does not preempt express warranty claims; *Michael v. Shiley*, 46 F.3d 1316 (3rd Cir. 1995): MDA does not preempt express warranty claims and fraud on the medical community and public.

Fourth Circuit: *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995): MDA does not preempt claims relating to non-FDA required representations made by the manufacturer.

Fifth Circuit: *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993): MDA preempts all state tort claims; *Reeves v. Acromed*, 44 F.3d 300 (5th Cir. 1995): MDA preempts all claims, even if manufacturer withholds information from FDA; *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995): MDA does not preempt design defect claims or implied warranty claims based on defective design.

Eighth Circuit:	*Martello v. CIBA Vision*, 42 F.3d 1167 (8th Cir. 1994): MDA preempts all state law claims.
Ninth Circuit:	*Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995): MDA does not preempt any state law claims of general applicability to products in addition to medical devices.
Eleventh Circuit:	*Lohr v. Medtronic, Inc.*, 56 F.3d 133 (11th Cir. 1995), cert. granted Jan. 19, 1996: MDA preempts all claims except those for negligent design and strict liability.

Against this tapestry of confusion and irreconcilable conflict, on January 19, 1996 the Supreme Court granted the petitions for writ of certiorari filed by both parties in *Lohr v. Medtronic, Inc.*, No. 95-886 and No. 95-754.

III. THE COURT OF APPEALS' DECISION IS ERRONEOUS

A. As to Preemption Under the MDA

Curiously, the *Mitchell* court determined that by "requirements" of general applicability, Sec. 808.1(d) meant only *positive enactments of law*, not state tort and common law. In the same breath, the court of appeals then incongruously stated that state tort and common law ARE "requirements" under Sec. 360k(a). While the court of appeals notes that state tort or common law is not

specifically named under Sec. 808.1(d), it chooses to overlook the obvious reason: that by "requirement," Congress and the FDA meant positive enactments of law, not state tort and common law.[3]

The term "requirement" as used within the MDA statutory and regulatory scheme cannot have the split-personality meaning created by the Seventh Circuit in *Mitchell*; "requirement" cannot include state and common law for preemption purposes while simultaneously excluding them for non-preemption purposes (unless the court of appeals were to give effect to the two FDA regulations in point, which it chose not to do.)

Clearly, the Seventh Circuit found, if not perhaps created, an ambiguity as to whether "requirement" in Sec. 360k(a) means common law or only positive enactments of law. In doing so, the court of appeals ignored this Court's instructions that courts confronted with an ambiguous statute must defer to the interpretation of the federal agency responsible for enforcement of such statute.

The court did, however, give a passing nod to 21 U.S.C. Sec. 360h(d): "[I]t suffices to say that our holding today that not every state law claim is preempted under the MDA is consistent with the view that 21 U.S.C. Sec. 360h(d) saves at least some claims from MDA preemption." App. 14. Inexplicably, the appellate court failed to explain *which* claims were protected by Sec. 360h(d), or

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[3] The inclusion of court decisions as a "requirement" under 21 C.F.R. Sec. 808.1 is consistent with this, as a court can *enforce* a positive enactment of law.

why the provision had only a partial non-preemptive effect.

The FDA has made its position on the issue of MDA preemption of state and common law abundantly clear: there IS no such preemption. This is shown not only by Sec. 808.1(d), but by the FDA's Amicus Brief in *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995) (disagreeing with the First Circuit's preemption decision in *King v. Collagen Corporation*), and in the FDA's letters of March 8, 1984 and February 2, 1987.

B. As to the Summary Judgment Evidence and Burden of Proof Under *Celotex*

The Seventh Circuit held that Petitioners failed to present evidence of fraud, adulteration or breach of warranty to defeat summary judgment on the merits. This is an erroneous application of *Celotex v. Catrett*, 477 U.S. 317 (1986), as Collagen Corporation's motion only sufficiently raised the *legal* issue of preemption, not *factual* issues as to the underlying claims. In particular, the affidavit of Collagen Corporation's Ross Erickson failed in all respects to allege that the device was not adulterated, misbranded or mislabeled, or that Collagen Corporation had not comitted fraud.

The crux of this issue is: was Collagen Corporation's motion for summary judgment, which alleged as its sole ground the legal issue of preemption, sufficient to put at issue the underlying merits of the Mitchells' claims? Stated otherwise, is merely asserting in a motion for summary judgment that there are no fact questions, in a context where the plaintiffs can read it as meaning there

are no fact questions as to the affirmative defense of preemption, sufficient under *Celotex* to put at issue the underlying factual merits of the plaintiff's claims?

In ruling in favor of Collagen, the court of appeals violated *Celotex Corporation v. Catrett*, 477 U.S. 317 (1986) and created confusion and uncertainty. Collagen presented one and only one ground for summary judgment in its motion:

> Plaintiffs' claims are preempted by federal law, specifically the Medical Device Amendments to the Food, Drug & Cosmetic Act, 21 U.S.C. Sec. 360c, et seq., and regulations promulgated thereunder.

(Defendant's Motion for Summary Judgment, paragraph 3). Collagen Corporation never requested summary judgment on the merits of Petitioners' underlying claims, making instead an insufficient and generalized statement that there was no "genuine issue of material fact."

As this Court held in *Celotex*, it is not enough for the movant to rely on a conclusory statement that the nonmovant has not presented evidence on an essential element; it must specifically point out to the court the nonexistence of evidence on such essential element.[4]

As to Petitioners' adulterated device claims, the court of appeals relied on two sources of "evidence" that it

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[4] At page 20 of its Memorandum in Support of Defendant's Motion for Summary Judgment, Collagen sufficiently followed *Celotex* solely as to any claims that Zyderm was not in compliance with PMA specifications; however, this allegation was insufficient to put Petitioners on notice as to a factual dispute regarding any other particular cause of action. *Celotex*.

states Petitioners failed to refute: first, Collagen's statement in the motion for summary judgment that "[t]here is no evidence to support Barbara Mitchell's claim for . . . adulteration" (App. at 28), and second, the Affidavit of Collagen Corporation's Ross Erickson, which alleged "neither Zyderm not Zyplast was ever determined by the FDA to be either mislabeled or adulterated ("App. at 28). As to fraud by Collagen in its device promotionals and advertisement, the Seventh Circuit stated that

> Collagen, through the exhibits attached to the affidavit of Ross Erickson, established that the FDA had placed restrictions on Collagen's advertising and promotional materials. The Mitchells did not introduce affidavits, depositions or other materials either to rebut Collagen's submissions or to demonstrate that there were genuine issues with respect to other promotional materials.

App. at 32-33. That the FDA had general restrictions on Collagen's promotionals, or that it had not ever determined Zyderm to be adulterated, was not sufficient to require Petitioners to prove the merits of their underlying claims. The court of appeals does not explain just how it is that existence of FDA advertisement restrictions acts to absolve Collagen from claims of fraud regarding its advertisements, or how a lack of any finding as to adulteration somehow rises to the level of establishing that the device was *not* adulterated.

The court of appeals ignored *Celotex*, in that Collagen's motion failed to properly put fraud, adulteration, or warranty claims at issue; indeed, it only sufficed to raise the legal issue of preemption.

Should this Court grant writ herein and hold that Petitioners' claims, wholly or partially, are not preempted by the MDA, then Petitioners would respectfully request the Court to also reverse the summary judgment as to the merits of Petitioners' underlying claims to the extent they are not preempted.

IV. THE ISSUE IS PROFOUNDLY IMPORTANT

By granting the petitions for writ in *Lohr*, the Court has made it clear that this issue of MDA preemption of state tort law is one of significant if not profound importance.

While *Lohr, Duvall, English* and *Feldt* involve the question of MDA preemption as to Sec. 510(k) "substantially equivalent" devices, the Mitchells' Petition here involves an ordinary PMA-approved Class III device. As it is complementary but not identical to *Lohr* (and *Duvall, English* and *Feldt*), this Petition presents the Court with an opportunity to address and resolve both regulatory-facets of the MDA-preemption issue in a non-multifarious manner.

CONCLUSION

The Mitchells respectfully request that this petition for writ of certiorari be granted.

Respectfully submitted,

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In the

United States Court of Appeals

For the Seventh Circuit

No. 94-3946

BARBARA MITCHELL AND GREGORY MITCHELL

Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Indiana, Hammond Division.
No. 93 C 283 – James T. Moody, *Judge.*

ARGUED May 19, 1995 – DECIDED OCTOBER 2, 1995

Before CUDAHY, RIPPLE and KANNE, *Circuit Judges.*

RIPPLE, *Circuit Judge.* In this case, Barbara and Gregory Mitchell appeal the district court's decision denying them leave to amend their complaint and dismissing their state law claims on the ground that they were all preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c-360l. For the reasons that follow, although we conclude that some state law claims are not preempted by the MDA, we affirm the judgment of the district court.

I

BACKGROUND

A. *Facts*

In 1988, Barbara Mitchell received several injections of Zyderm or Zyplast (collectively, "Zyderm"), collagen-based products produced by Collagen Corporation. These products are used to correct skin tissue anomalies such as wrinkles. Under the Medical Device Amendments, 21 U.S.C. § 360c-360l (MDA), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-395, Zyderm is classified as a "Class III medical device." Class III devices must be approved by the FDA before they may be sold to the public. 21 U.S.C. § 360c(a)(1)(C).

The premarket approval ("PMA") process is used to determine "the safety and effectiveness" of a device with respect to its intended users under the conditions "prescribed, recommended, or suggested" in its labeling. 21 U.S.C. § 360c(a)(2). As part of the PMA process, a manufacturer must submit samples of the device, an outline of the device's components and properties, a description of the manufacturing process, safety data, a bibliography of all reports concerning the device's safety and effectiveness, copies of all proposed labeling, and any other information the FDA requests. 21 U.S.C. § 360e(c); *see also* 21 C.F.R. § 814.20. The application is referred to a panel of qualified experts for study and submission of a report and recommendation respecting approval. 21 U.S.C. § 360e(c)(2); *see id.* § 360c(b)(2) (describing composition of panels). The FDA retains the right to withdraw its approval if it finds that a device previously approved is not safe and effective. 21 U.S.C. § 360e(e).

Zyderm's PMA initially was approved in 1981. The FDA approved the PMA for Zyplast, a derivative of Zyderm, in 1985. During 1991-1992, the FDA conducted a re-review of Zyderm and concluded in early 1992 that its PMA approval decision was appropriate.

B. *Earlier Proceedings*

Following her injections, Barbara Mitchell developed serious medical complications. In 1993, she and her husband filed suit against Collagen in Indiana state court. Their complaint included counts sounding in strict liability, negligence, fraud, mislabeling, misbranding, adulteration, and breach of warranty. Collagen removed the case to federal court. The Mitchells moved to amend their complaint to add a claim under Indiana's Deceptive Consumer Sales Act; Collagen filed for summary judgment on the ground that the Mitchells' claims were preempted by federal law.

The district court denied the Mitchells' motion for leave to amend. 870 F. Supp. 885, 887-89 (N.D. Ind. 1994). The court reasoned that amendment would be futile because the Mitchells' claim would be time-barred under the applicable limitations period. The district court further held that the Mitchells' claim was not saved by their allegation that Collagen had concealed fraudulently their claims. The court reasoned that, even if the Mitchells could rely upon a claim of fraudulent concealment to toll the applicable limitations period, such tolling would occur for only a "reasonable time." The court found the Mitchells' delay in filing suit unreasonable. It noted that the Mitchells knew that Zyderm was related to Barbara

Mitchell's injuries since at least 1991 and that they had delayed thirteen months between the time they acquired this information and the time they first filed suit against Collagen, and an additional twelve months before they sought to add the Deceptive Consumer Sales Act claim.

Next, the court determined that the Mitchells' remaining state law claims were preempted. 870 F. Supp. at 889-98. The court focused upon the MDA's preemption provision, which expressly proscribes states from establishing "any requirement . . . different from, or in addition to," the requirements established pursuant to the MDA. *See* 21 U.S.C. § 360k(a).[1] Regulations promulgated by the FDA explain that the state "requirements" preempted under section 360k(a) include those "established by statute, ordinance, regulation or court decision." 21 C.F.R. § 808.1(b). Relying upon the statutory preemption provision, the court reasoned that Congress intended the MDA amendments to have a broad preemptive effect – one that encompassed common law causes of action. It further reasoned that, in the case of Class III devices, the

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[1] The statute provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

detailed premarket approval procedures constituted applicable federal requirements that preempted all state laws that established standards "different from, or in addition to," the federal mandates. To the extent that the FDA's regulations, such as 21 C.F.R. § 808.1(d),[2] suggested that the MDA amendments preempted only those

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[2] The regulation provides, in pertinent part:

> State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by [21 U.S.C. § 360k(a)] because they are not 'requirements applicable to a device' within the meaning of section [360k(a)]. The following are examples of State and local requirements that are not regarded as preempted by section [360k(a)] of the act:
>
> (1) Section [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.
>
> * * *
>
> (6)(ii) Generally, section [360k(a)] does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if it is different from, or

state laws directed specifically at medical devices, the district court continued, they were inconsistent with congressional intent and entitled to no deference.

II

DISCUSSION

There are two basic issues on appeal. First, we must determine whether the district court erred in denying the Mitchells leave to amend their complaint. We review the district court's decision for abuse of discretion. *Cleveland v. Porca Co.*, 38 F.3d 289, 297 (7th Cir. 1994). Second, we must consider whether the district court properly granted Collagen summary judgment on the ground that the Mitchells' remaining state law claims were preempted. We review the district court's grant of summary judgment de novo. *Green v. Shalala*, 51 F.3d 96, 99 (7th Cir. 1995). Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Id.*; *see generally Doe v. R.R. Donnelley & Sons Co.*, 42 F.3d 439, 443-44 (7th Cir. 1994).

A. *Denial of Leave to Amend*

The Mitchells submit that the district court abused its discretion in denying their motion for leave to amend their complaint. Federal Rule of Civil Procedure 15(a) directs the district courts freely to allow leave to amend a complaint "when justice so requires." Fed.R.Civ.P. 15(a).

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in addition to, a Federal requirement established under the act.

21 C.F.R. § 808.1(d).

However, district courts need not entertain futile amendments to the pleadings. *Moore v. State of Ind.*, 999 F.2d 1125, 1128 (7th Cir. 1993); *DeSalle v. Wright*, 969 F.2d 273, 278 (7th Cir. 1992). Thus, the district court does not abuse its discretion in denying leave to amend when the proposed amendment could not withstand a motion to dismiss. *See Bower v. Jones*, 978 F.2d 1004, 1008 (7th Cir. 1992) ("An amendment is futile when it . . . could not withstand a motion to dismiss."); *see also* Moore, 999 F.2d at 1128.

In this case, the Mitchells sought leave to add a claim against Collagen under the Indiana Deceptive Consumer Sales Act. Such claims are subject to a two-year occurrence limitations period. *See* Ind. Code § 24-5-0.5-5(b) ("Any action brought under this chapter may not be brought more than two (2) years after the occurrence of the deceptive act[.]"). Collagen notes that, in this case, the two-year period began to run no later than September 1988, when Barbara Mitchell received her final injection. Therefore, Collagen contends, the limitations period expired well before the Mitchells filed suit in 1993. The Mitchells respond, however, that Collagen should be estopped from raising the limitations period as a defense because Collagen fraudulently concealed their cause of action from them. Collagen replies that the Mitchells should not receive any equitable extension of the limitations period because their delay in seeking leave to amend was unreasonable.

Under Indiana law, when grounds such as fraudulent concealment exist for estopping a defendant from raising the expiration of the statute of limitations as a defense, a limitations period may be extended in equity to allow a plaintiff a reasonable time within which to file suit. *See,*

e.g., Babcock v. Lafayette Home Hosp., 587 N.E.2d 1320, 1324 (Ind. Ct. App. 1992). This equitable extension, however, does not resurrect the full limitations period for the plaintiff. Rather, it affords the plaintiff merely a "reasonable period" in which to file suit. *Id.; Yarnell v. Hurley*, 572 N.E.2d 1312, 1315 (Ind. Ct. App. 1991); *see also Cacdac v. Hiland*, 561 N.E.2d 758, 759 (Ind. 1990).

Applying these principles, we cannot say that the district court abused its discretion by denying the Mitchells leave to amend. The Mitchells rely on Collagen's alleged fraudulent concealment as the basis for seeking an extension of the applicable limitations period. However, the Mitchells' own complaint makes clear that they knew Collagen might be the source of their injuries by late 1991. *See* Complaint, R.1, Ex.A at 3, Count I, ¶ 10 ("Plaintiffs Barbara and Gregory Mitchell learned that there was a relationship between Defendant Collagen Corporation's products and her injuries in the fall of 1991."). The Mitchells do not explain why they waited twenty-five months after first acquiring this knowledge, or, more particularly, over twelve months after first filing suit against Collagen, to seek leave to add their claim under the Indiana Deceptive Consumer Sales Act. Consequently, the district court did not abuse its discretion in denying leave to amend. The Mitchells' unexplained delay was not reasonable, and, therefore, there would have been no basis for extending the expired limitations period to save their time-barred claim. *Cf. Babcock*, 587 N.E.2d at 1324-25 (finding unreasonable plaintiff's unexplained failure to file suit until over one year after learning defendant had injured her).

B. *Preemption*

1.

We begin with a review of the principles that govern preemption analyses. Under the Supremacy Clause, "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Pursuant to this authority, the Congress may preempt state law. *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 368 (1986). "Whether federal law pre-empts a state law establishing a cause of action is a question of congressional intent." *Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2243 (1994); *see Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992); *see also CSX Transp., Inc. v. Easterwood*, 113 S. Ct. 1732, 1737 (1993) (stating that pre-emption "will not lie unless it is 'the clear and manifest purpose of Congress' ") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

As the Supreme Court noted in *Easterwood*, evidence of preemptive purpose "is sought in the text and structure of the statute at issue." 113 S. Ct. at 1737. "If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id.* Indeed, the existence of an express preemption clause supports an inference that Congress intended to limit the federal statute's preemptive scope to the express terms of the clause, although it "does not mean that the express clause entirely forecloses any possibility of implied preemption." *Freightliner Corp. v. Myrick*, 115 S.

Ct. 1483, 1488 (1995) (discussing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608 (1992)). "Pre-emption . . . is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1982) (quotations and citation omitted).

2.

We now apply these principles to the MDA. The MDA contains an express preemption provision, 21 U.S.C. § 360k(a), that provides:

> Except as provided in subsection (b) of this section [not relevant in this case], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

a.

Our first task is to determine whether the phrase "any requirement" encompasses state common law causes of action. Collagen submits that the Supreme Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S.

504, 112 S. Ct. 2608 (1992), makes clear that Congress' preemption of state "requirements" encompasses common law causes of action. In *Cipollone*, the Court considered the scope of the preemption provision in section 5(b) of the Public Health Cigarette Smoking Act of 1969, which provided, in pertinent part:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

See id. at ___, 112 S. Ct. at 2617 (quoting statute). A majority of the Justices agreed that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules." *Id.* at ___, 112 S. Ct. at 2620 (plurality op. of Stevens, J., joined by The Chief Justice, and White and O'Connor, JJ.); *see also id.* at ___, 112 S. Ct. at 2634 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part). These same Justices also agreed that the phrase "imposed under State law" included not only state statutes and regulations, but state common law as well. *Id.* at 2620 (plurality), *id.* at 2634 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part).

Cipollone suggests that 21 U.S.C. § 360k(a)'s preemption of state "requirement[s]" "different from, or in addition to," those of the MDA is broad enough to include state common law causes of action. This view is buttressed by an FDA regulation that interprets the statute's

preemptive sweep as encompassing state requirements established by "statute, ordinance, regulation, or *court decision*." 21 C.F.R. § 808.1(b) (emphasis added). Indeed, these interpretive guides have led every circuit that has considered the question to conclude that 21 U.S.C. § 360k(a) preempts at least some common law causes of action.[3] Moreover, although we did not specifically discuss the scope of the "any requirement" clause, our decision in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1332-34 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992), which held various common law causes of action against a manufacturer of intraocular lenses preempted by regulations promulgated under the MDA, certainly comports

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[3] *See, e.g., Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *2 (1st Cir. Aug. 14, 1995); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1323 & n. 4 (3d Cir. 1995) ("[T]he term 'requirements' as used in § 360k encompasses state common law claims."), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir.) (relying upon Cipollone), *cert. denied*, 115 S. Ct. 429 (1994); *Feldt v. Mentor Corp.*, 61 F.3d 431, 433 n. 2 (5th Cir. 1995); *Reeves v. Acromed Corp.*, 44 F.3d 300, 304 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1420-21 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 991 (8th Cir. 1994) (holding that Congress' use of "requirement" evinced an intent for broad preemption of state tort laws); *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995) ("In promulgating the MDA, Congress expressly intended to preempt state tort law."); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995) ("Every circuit to consider the question agrees that common law actions are state requirements within the meaning of § 360k(a).").

with the reasoning of these other circuits. Further, our decision in *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370-71 (7th Cir. 1993) relied explicitly upon *Cipollone* to hold that the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), which forbids states from imposing labeling requirements "in addition to or different from" federal requirements, preempted various common law claims. We see no reason to depart from these authorities, and we therefore make explicit that which was at least implicit in *Slater:* The phrase "any requirement" in 21 U.S.C. § 360k(a) is broad enough to include at least some common law causes of action within the statute's preemptive scope.

b.

i.

The Mitchells seek to avoid the result dictated by the precedents discussed above. They note that another provision of the MDA states that

> [c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 U.S.C. § 360h(d). The Mitchells submit that this portion of the MDA "saves" all common law causes of action from preemption. We cannot accept this contention. Although the existence of both a preemption provision and a savings clause in a federal statute indicates that Congress did not intend to preempt the field, *American*

Agric. Movement, Inc. v. Board of Trade, 977 F.2d 1147, 1155 (7th Cir. 1992), "where the preemptive intent of Congress is clear, a general savings clause cannot supersede the specific preemption provision." *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995) (analyzing 21 U.S.C. § 360h(d)) (citing *Morales*, 504 U.S. at 383-85). As we have noted above, the case law makes clear that Congress' reference to state "requirements" in preemption legislation evidences an intent to preempt at least some common law causes of action. Thus, we cannot agree that 21 U.S.C. § 360h(d) saves all such claims from preemption. At best, this provision saves some state law claims. *See Lohr*, 56 F.3d at 1343-44. However, nothing in the statute suggests which claims Congress meant to save. It is this question that we shall explore in the later pages of this opinion. At this point, in answer to the Mitchells' submission, it suffices to say that our holding today that not every state law cause of action is preempted under the MDA is consistent with the view that 21 U.S.C. § 360h(d) saves at least some claims from MDA preemption.

ii.

The Mitchells also invite our attention to an FDA regulation that provides that 21 U.S.C. § 360k(a):

> does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d). The Mitchells contend that this regulation saves all common law causes of action. They submit that the regulation constitutes a reasonable construction of the MDA and that it therefore is entitled to deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

Under *Chevron*, the first step in interpreting a federal statute is to determine whether its meaning is unambiguous; if Congress has spoken on the precise question at issue and its intent is clear "that is the end of the matter." *Id.* at 842. However, if the statute is silent or ambiguous with respect to the issue in question, we are obliged to defer to the interpretation provided by the agency charged with the responsibility of administering the statute, as long as the agency's interpretation is reasonable. *Id.* at 843. The FDA is charged with the responsibility of administering the MDA. 21 U.S.C. § 371(a). Accordingly, the FDA's interpretations of ambiguous MDA provisions are entitled to deference under *Chevron*.

The scope of the phrase "any requirement" in 21 U.S.C. § 360k(a) is not completely unambiguous;[4] we are therefore justified in looking to the regulation to ascertain its meaning. Nevertheless, we cannot accept the Mitchells' argument that 21 C.F.R. § 808.1(d)(1) saves all

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[4] *See, e.g., Lohr*, 56 F.3d at 1343-45 (concluding that meaning of "requirement" in § 360k(a) was not so clear and unambiguous as to preclude reliance upon FDA requirement, set forth in another portion of 21 C.F.R. § 808.1(d), that there must be specific MDA regulations or requirements relating to the medical device in question in order for state law claims to be preempted).

common law causes of action from preemption under the MDA. We believe that it is far more reasonable to read this regulation more narrowly. We note at the outset that the regulation does not speak to common law claims; its reference to requirements of "general applicability" is not to common law causes of action but to electrical codes and the U.C.C. – positive enactments of law. Indeed, section 808.1(d), listing various state requirements that are not preempted by the statute, is noticeably silent on the matter of state tort claims when read in its entirety. *See Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543 n. 2 (3d Cir.) ("21 C.F.R. § 808.1(d) sets forth examples of state or local requirements that are not preempted by § 360k. Significantly, the list of requirements exempted from § 360k does not include state tort or common law claims."), *cert. denied*, 115 S. Ct. 429 (1994); *cf. Slater*, 961 F.2d at 1333-34 (concluding, in case not involving analysis of 21 C.F.R. § 808.1(d)(1), that MDA preempted some, but not all, state law causes of action of general applicability). Indeed, if we were to give 21 C.F.R. § 808.1(d) the breadth which the Mitchells urge that we give it, we would contradict squarely the manifest intent of the statute which, as we have already noted, clearly evidences a congressional intent to preempt some common law causes of action. Cipollone teaches that, when Congress uses phraseology almost identical to that used in 21 U.S.C. § 360k(a), it evidences an intent to preempt at least some common law causes of action. Our decision in *Shaw* confirms this view. *See Shaw*, 994 F.2d at 370-71. Under these circumstances, we would be obliged to give no deference to such an expansive reading of the regulation. "The judiciary is the final authority on issues of statutory

construction and must reject administrative constructions which are contrary to clear congressional intent." *Chevron*, 467 U.S. at 843 n. 9.

Accordingly, we cannot accept the view that 21 U.S.C. § 360k(a) may reasonably be read as failing to encompass *any* common law cause of action of general applicability. *Cf. Michael v. Shiley, Inc.*, 46 F.3d 1316, 1323 n. 4 (3d Cir. 1995) (noting, without expressing a view on the validity of the regulation, that "[d]espite the reference in 21 C.F.R. § 808.1(d)(1) to laws of general applicability, we hold that the statutory language of § 360k preempts Michael's claims for breach of the implied warranties of merchantability and fitness[.]"), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971).[5]

3.

Having determined that 21 U.S.C. § 360k(a) is broad enough to preempt at least some common law causes of action, we now consider the precise scope of this preemption provision. Initially, we note that the language in 21 U.S.C. § 360k(a)(2) providing that the state "requirements" must "relate[] to the safety or effectiveness of the device or to any other matter in a requirement applicable to the device" under the MDA does not cabin significantly the preemptive sweep of the statute. In *American*

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[5] The Eleventh Circuit's decision in *Lohr*, which found the scope of § 360k(a) ambiguous for purposes of deferring to another portion of 21 C.F.R. § 808.1(d), does not conflict with this reasoning; indeed, the Eleventh Circuit specifically held that some types of common law claims of general applicability were preempted by the MDA. *See* 56 F.3d at 1350-51.

Airlines, Inc. v. Wolens, 115 S. Ct. 817 (1995), the Supreme Court recently emphasized that, when Congress uses the phrase "relates to" in a preemption provision, the phrase should be construed broadly. *See id.* at 821 (defining the phrase "relates to" as "having a connection with or reference to") (citing *Morales v. Trans World Airlines*, 112 S. Ct. 2031, 2037 (1992); *Shaw v. Delta Air Lines*, 463 U.S. 85, 97 (1983)). We must also consider the breadth of the language in § 360k(a). It expressly preempts claims relating not only to "safety and effectiveness," but also to *"any other matter* included in a requirement," 21 U.S.C. § 360k(a)(2) (emphasis added). The section therefore encompasses state law claims that add requirements "different from, or in addition to," any requirement set forth in the MDA. *See* Michael, 46 F.3d at 1330-31; *cf. Cipollone*, 505 U.S. at ___, 112 S. Ct. at 2621 (plurality op.) (focusing upon whether legal duty serving as predicate for state law action was based upon smoking and health where preemptive sweep of statute was limited to state laws based upon smoking and health).

The Mitchells' chief contention, however, does not concern whether their state law claims "relate to" some MDA requirement applicable to Zyderm; rather it concerns whether such a "requirement" exists. The Mitchells focus upon a portion of 21 C.F.R. § 808.1(d) that provides:

> [S]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different

> from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d). This regulation makes clear, the Mitchells contend, that common law causes of action survive preemption unless the FDA has established "specific counterpart regulations" or "other specific requirements" for the medical device in question. They submit that, because no such "regulations" or "requirements" exist with respect to Zyderm, none of their common law causes of action are preempted.

In response, Collagen does not challenge the validity of the FDA regulation. *Cf. Lohr*, 56 F.3d at 1343-45 (holding that this portion of 21 C.F.R. § 808.1(d) is entitled to deference). Rather, it contends that the detailed premarket approval process constitutes a "specific requirement" applicable to Zyderm and other Class III medical devices. Therefore, Collagen contends, any state laws that seek to add requirements "different from, or in addition to," the premarket approval process are preempted under the MDA.

Although the Mitchells correctly note that the FDA has issued no regulation or requirement relating exclusively to Zyderm, we cannot accept their argument. Our colleagues in the Eleventh Circuit recently explained the fallacy inherent in the argument that the FDA's premarket approval process does not constitute a "specific requirement" for purposes of 21 C.F.R. § 808.1(d):

> The most natural reading of the FDA's "specific requirements" language requires specificity in the nature of the requirements, not in their applicability to designated devices. The "applicable to a particular device" language,

> mirroring the statute, requires a court to ask whether the requirements in question apply to the device in question. . . .
>
> Construing the FDA's preemption regulations to require device specificity also contradicts the structure of the Act. Under the MDA, Class III devices are subject to the highest level of scrutiny through the PMA process. . . . Yet the PMA procedure's "requirements" under the MDA are not device-specific. Instead, the PMA process requires manufacturers to submit to an approval process standardized for all Class III devices. . . . It would be anomalous for the MDA to preempt certain claims which conflict with device-specific requirements placed on Class II devices . . . but not preempt claims against devices subject to the MDA's most rigorous, albeit non-device-specific, procedures.

Lohr, 56 F.3d at 1345-46 (internal footnotes and citations omitted). We agree with this reasoning and conclude that the premarket approval process constitutes a "specific requirement" for purposes of 21 C.F.R. § 808.1(d) and 21 U.S.C. § 360k(a). In doing so, we align ourselves with the majority of circuits to have considered this question.[6]

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[6] *See, e.g., Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir. 1995) (noting that premarket approval procedures present "specific requirements applicable to a particular device under the act"), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994) ("The premarket approval process is a specific requirement for a device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d)."), *cert. denied*, 115 S. Ct. 2614 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-22 & n. 3, 1424 & n. 8 (5th Cir.) (stating, in case involving Zyderm, that

4.

We now must analyze each of the Mitchells' claims against Collagen to determine whether they would add

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the "Class III PMA process" is a "specific requirement" for purposes of § 808.1(d)), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.) (op. of Torruella, J., joined by Aldrich and Campbell, JJ.) ("FDA regulations provide that preemption does not apply when the FDA has issued no regulations or other requirements specific to the particular device. . . . In this case, it is clear that the FDA has imposed requirements on *Zyderm* related to labeling, design, manufacturing and other aspects of the device pursuant to the MDA scheme.") (emphasis added), *cert. denied*, 114 S. Ct. 84 (1993); *see also Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1346 (11th Cir. 1995) (noting agreement with rationale that PMA process constitutes a "specific requirement" for purposes of § 808.1(d) in case involving Class III device exempted from the PMA process); *cf. Feldt v. Mentor Corp.*, 61 F.3d 431, 436 & n. 5 (5th Cir. 1995) (noting, in case involving Class III device not subject to PMA process, that FDA requirements need not be device-specific) (*citing Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) (Class II device case)). *But cf. LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846, 855 (2d Cir. 1994) (rejecting MDA preemption argument "substantially for the reasons stated by the district court in its opinion"; district court, 834 F. Supp. 576, 582-85 (D.Conn.1993), concluded that no specific requirements existed with respect to a device that ultimately had been classified as a Class III device, but which had not been subjected to PMA process at the time it was implanted into the plaintiff).

The Ninth Circuit's decision in *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995), has been cited as adopting the rule advocated by the Mitchells in this case. *See Lohr*, 56 F.3d at 1346. *Anguiano* involved a Class II medical device that, by definition, was not subject to the PMA process. Although the court in *Anguiano* did state that "the scope of preemption is limited to instances where there are specific FDA

requirements "different from, or in addition to," the PMA process or other FDA requirements and therefore be preempted. Collagen submits that all of the Mitchells' claims are preempted. The Mitchells contend that recent court decisions have made clear that at least their fraud, misrepresentation, and breach of warranty claims survive preemption. In response, Collagen argues that the Mitchells may not benefit from these decisions because they have not made a sufficient summary judgment record.

a. Strict Liability & Negligence Claims

At the outset, we note that the Mitchells do not contend seriously that their strict liability and negligence claims would neither "establish [n]or continue in effect" a requirement "different from, or in addition to," the requirements involved in the PMA process. Read generously, their brief addresses these claims only in its section presenting the argument that 21 C.F.R. § 808.1(d) saves all common law causes of action from preemption. *See*

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requirements applicable to a particular device," 44 F.3d at 809 (quotations and citations omitted), the court later noted that the "argument that the MDA regulatory framework preempts state law, even absent specific provisions, applies only to Class III devices, not Class II devices." *Id.* at 810. The latter statement suggests that the Ninth Circuit's position comports with the majority of other circuits, at least with respect to Class III devices. Indeed, the court in *Anguiano* cited to decisions from the First and Fifth Circuits to support the statement referred to by *Lohr*, yet, as is indicated above, the First and Fifth Circuits have concluded that the premarket approval process constitutes a "specific requirement" applicable to "particular device[s]" for purposes of 21 C.F.R. § 808.1(d).

Appellant's Br. at 15-21. As we noted above, that argument is flawed.

In any event, these claims are preempted by the MDA. The Mitchells' strict liability claim consists of allegations that Zyderm was "an unreasonably dangerous product" and that Collagen "knew or in the course of reasonable care should have known" that Zyderm "was unreasonably dangerous and had the potential for causing serious immunological and/or autoimmune reactions, damage and injuries when injected into humans for its intended use and purpose." *See* R.1, Ex.A at 2-3, Count I, ¶¶ 7, 9. The complaint alleges the following negligence claims: "inadequate warnings accompanied" Zyderm, *id.* at 2, Count I, ¶ 8, and "Collagen Corporation was negligent in the design, testing, approval, manufacturing, marketing and sale" of Zyderm, *id.* at 5, Count IV, ¶ 2.

We agree with several other circuits which have considered the issue that, with respect to a Class III device that has undergone the PMA process, such claims are preempted because they undoubtedly would add requirements "different from, or in addition to," those set forth in the MDA.[7] "FDA approval of a premarket application

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[7] *See, e.g., Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir. 1995) (*citing Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543-44 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994), for the proposition that "state law negligence and strict product liability claims are pre-empted under § 360k on account of the potential conflict with FDA labeling, design, and manufacturing requirements"), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994) (strict products liability and negligent instruction, labeling, warning, and testing claims), *cert. denied*, 115 S. Ct.

shows the FDA has reviewed a device's testing, design specifications, intended use, manufacturing method, performance standard, and labelling, . . . and decided the

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2614 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 & n. 5 (5th Cir.) (failure to warn, defective design, and defective manufacturing claims), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1135-36 (1st Cir. 1993) (op. of Torruella, J., joined by Aldrich and Campbell, JJ.) (strict liability and negligent design, manufacturing, marketing, and sales claims), *cert. denied*, 114 S. Ct. 84 (1993); *see also Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *6 (1st Cir. Aug. 14, 1995) (adopting analysis of district court, which held claims for negligent design, development, and manufacture preempted); *Lewis v. Intermedics Intraocular, Inc.*, 56 F.3d 703, 708 (5th Cir. 1995) (noting, in intraocular lens case, "[i]f plaintiffs' products liability claims for recovery due to the lenses' dangers are preempted, then it would seem ridiculous to say that a claim for failure to warn about these dangers could survive"); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18-19 (1st Cir. 1994) (negligent failure to warn and negligent manufacturing claims preempted for Class III device not subject to PMA process); *cf. Feldt v. Mentor Corp.*, 61 F.3d 431, 436 & n. 6 (5th Cir. 1995) (holding, with respect to Class III device not subject to PMA process, that negligent marketing and inadequate warning claims were preempted, but defective design claim was not preempted because no FDA design requirement existed); Lohr, 56 F.3d at 1347-52 (11th Cir. 1995) (holding, with respect to Class III device that had not undergone PMA process, that negligent design and strict liability claims were not preempted, but that MDA's good manufacturing regulations, warning, and labeling requirements nonetheless preempted negligent manufacture and negligent failure to warn claims).

In *Reeves v. Acromed Corp.*, 44 F.3d 300, 304-05 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995), the Fifth Circuit held that failure to warn claims were preempted by the MDA with respect to a Class III device not subject to the PMA process. The opinion indicates that various negligent design and manufacturing defect claims went to the jury during the district court

device is safe and effective." *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995) (citing 21 U.S.C. §§ 360c(a)(2), 360e(c)(1)); *see also* Ministry of Health, Province of *Ontario, Can. v. Shiley, Inc.*, 858 F. Supp. 1426, 1438-39 (C.D. Cal. 1994) (stating that "a finding of negligence would mean implicitly finding that the FDA approval was not good enough," and that a successful strict liability claim would require a court to hold that the product was unsafe and dangerous "in opposition to the contrary determination made by the FDA"); *cf. Slater*, 961 F.2d at 1332-33 (indicating that claims for inadequate testing, defective design, and failure to warn were preempted in case involving device not subject to PMA process).

b. Mislabeling, Misbranding, and Adulteration

i.

The Mitchells' complaint also alleged that Zyderm was a "mislabeled and/or adulterated product." R.1, Ex.A at 5, Count IV, ¶ 2. To the extent that this allegation charges that Zyderm, despite conformity to the FDA's premarket approval process, was mislabeled, misbranded, or adulterated, the Mitchells' claim would be preempted for the reasons discussed in the previous subsection. In essence, the claim would seek to add requirements "different from, or in addition to," those established through the FDA's premarket approval process. *See Martello*, 42 F.3d at 1169; *see also Slater*, 961 F.2d

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proceedings, but does not comment upon whether such claims are or are not preempted under the MDA. *See id.* at 307-08.

at 1332-34; *cf.* 21 C.F.R. § 808.1(d)(6)(ii) (noting that state requirements prohibiting manufacture of misbranded and adulterated devices are preempted to the extent they establish substantive requirements "different from, or in addition to, a Federal requirement established under the act").

On the other hand, it is possible to view the Mitchells' claim as alleging that Zyderm was mislabeled or adulterated because Collagen failed to meet the labeling and purity standards established *by* the PMA process. Various circuits have suggested that this is a distinction without a difference – such claims are nonetheless preempted.[8] A principal tenet of these decisions is that a court applying state law to ensure compliance with the

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[8] *See, e.g., Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265 at *4-6 (1st Cir. Aug. 14, 1995) (analyzing fraud against the FDA claim, but reasoning generally that any state law suit based upon a claim that the defendant had failed to comply with the MDA would be preempted because "if state courts erred in their application of the MDA, they would effectively be imposing requirements 'different from, or in addition to' those imposed by federal law"); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995) ("[P]reemption under the MDA cannot be defeated by a common-law suit alleging a violation of the statutory standards."); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.) (noting, with respect to intraocular lens device, that adulteration claim based on failure to meet FDA standards was preempted; "[t]he FDA can determine an investigational device to be adulterated if requirements under [applicable regulations] are not complied with"), *cert. denied*, 115 S. Ct. 429 (1994); *cf. Reeves v. AcroMed Corp.*, 44 F.3d 300, 307 & n. 4 (5th Cir.) ("We . . . decline . . . to create an unwieldy exception . . . in cases where manufacturers . . . violate FDA regulations."), *cert. denied*, 115 S. Ct. 2251 (1995).

federal standards may get the federal standards wrong and, therefore, end up imposing a requirement "different from or in addition to" the requirements established under the MDA. *See Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *4 (1st Cir. Aug. 14, 1995).

When the claim is that a particular product is adulterated because it does not comply with standards explicitly established by the FDA or that a particular label does not comply with standards explicitly established by the FDA, the correctness of this approach is not self-evident. In such circumstances, the existence of the FDA-approved paradigm appears to ensure that state law cannot impose requirements "different from or in addition to" federal law. The Eighth Circuit has stated that, "when a statute only preempts state requirements that are different from or in addition to those imposed by federal law, plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements." *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 993 (8th Cir. 1994); *see also Martello*, 42 F.3d at 1169 ("Martello did not claim the AOSEPT he used did not comply with federal regulations[.]"); *cf. Slater*, 961 F.2d at 1334 (commenting that the scope of MDA preemption is "limited to efforts by states to impose sanctions for compliance with federal regulations[.]"). In the absence of more explicit legislative or regulatory direction,[9] we hesitate to say,

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[9] We note that the existing regulations, albeit laconic, presently lend some support for the view that an adulteration claim based on a product's failure to meet PMA standards survives MDA preemption. *See* 21 C.F.R. § 808.1(d)(2) (stating that state or local requirements "equal to, or substantially identical to," federal requirements imposed under the MDA are not preempted).

therefore, that an adulteration claim based on a product's failure to meet PMA standards – standards that have been explicitly set forth by the FDA – does not survive MDA preemption. Such a claim seeks merely to enforce the federal standard, not to add requirements "different from, or in addition to," it.

ii.

The Mitchells' summary judgment filings suggest that their mislabeling and misbranding claims were directed at the labeling and branding of Zyderm generally, *see, e.g.*, R.12 at 13, and therefore were preempted for the reasons discussed above. Their adulteration claim seems to have concerned Zyderm's alleged failure to meet the performance standards set forth in its PMA. *See id.* at 14. Nevertheless, even construing the Mitchells' claim in this fashion, we hold that the district court did not err in granting Collagen summary judgment because Collagen established that there was no genuine issue of material fact that Zyderm was unadulterated. In its statement of material facts "in which there [was] no genuine issue," Collagen contended that "[t]here is no evidence to support Barbara Mitchell's claim for mislabeling and/or misbranding and/or adulteration." R.5 at 3 ¶ 18. Collagen supported this claim with an affidavit from Ross Erickson, Collagen's Vice President for Regulatory Affairs and Quality Assurance. Mr. Erickson asseverated that:

> Prior to 1988, and during that period of time in 1988 when plaintiff Barbara Mitchell was being treated with Zyderm and Zyplast, neither Zyderm nor Zyplast was ever determined by the FDA to be either mislabeled or adulterated. Any

> such citation would be in the records for which I have primary responsibility.

R.3, Aff. of R. Erickson ¶ F. In response to these submissions, the Mitchells stated that they "would dispute the veracity and/or materiality of Defendant Collagen Corporation's alleged material facts, in particular as to allegation number[ ] 18." R.13 at 2 ¶ 3. However, the Mitchells introduced no affidavits, depositions, or other materials to counter the Erickson affidavit.

Although the Mitchells contended at oral argument, as well as in their brief, that such submissions were unnecessary because the district court was ruling on purely legal issues, the Record makes clear that Collagen argued in the district court not only that adulteration claims should be preempted per se, but also that no genuine issue of material fact existed with respect to the Mitchells' adulteration claim. Indeed, the district court explicitly ruled that Collagen alternatively was entitled to summary judgment on the adulteration claim because the Mitchells had "pointed to no evidence of adulteration upon which they could go to a jury." 870 F. Supp. at 897. The Mitchells' failure to come forward with any evidence in response to Collagen's submission that there was no genuine issue of material fact with respect to the adulteration claim entitled Collagen to summary judgment. *See Doe v. R.R. Donnelley & Sons Co.*, 42 F.3d 439, 443 (7th Cir. 1994). "[S]ummary judgment must be entered 'against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.' " *Id.* (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

c. Fraud and Misrepresentation

The Mitchells' complaint raised two distinct claims for fraud and misrepresentation:

> Collagen Corporation[ ] procured approval to market and sell the named products through fraud and misrepresentation. Defendant, Collagen Corporation[,] markets and sells the named products through fraud and misrepresentations, by act and/or omission.

R.1, Ex.A at 5, Count IV, ¶ 2. The allegation in the first sentence constitutes a claim that Collagen defrauded the FDA to obtain approval to sell Zyderm; the second sentence alleges that Collagen committed fraud in the course of selling its product.

i.

The Mitchells' "fraud on the FDA" claim is preempted. As the Third Circuit recently noted, such claims seek

> to encourage the district court to review the PMA application [the defendant] submitted to the FDA. This inquiry could ultimately require that a court determine whether the information . . . submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations. In sum, this claim requires a court, applying state law, to perform the same functions initially entrusted to the FDA.

Michael v. Shiley, Inc., 46 F.3d 1316, 1329 (3d Cir. 1995), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971). We agree with the Third Circuit that 21 U.S.C. § 360k(a) "does not permit such a searching state inquiry into the inner workings of FDA procedures." *Id.*; *accord Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *3 (1st Cir. Aug. 14, 1995); *Reeves*, 44 F.3d at 306. "Surely, where the FDA was authorized to render the expert decision on Collagen's use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions. Further, if the court erred, and incorrectly posited the effect on the FDA's use and labeling decision, this would impose a state requirement 'which is different from, or in addition to, any requirement applicable . . . to the device.' " *King*, 983 F.2d at 1140 (Aldrich and Campbell, JJ., concurring) (quoting 21 U.S.C. § 360k(a)).

ii.

With respect to the Mitchells' other fraud claim, we note first that, in the district court, the Mitchells did not specify the nature of Collagen's alleged fraudulent statements or misrepresentations. *Cf.* Fed. R. Civ. P. 9(b). The district court viewed their claim as one alleging that Collagen's packaging and labeling were misleading; in other words, the court considered the claim as equivalent to the misbranding and mislabeling claims. *See* 870 F. Supp. at 897. Therefore, for the reasons set forth in our earlier discussion of mislabeling, misbranding, and adulteration, the district court concluded correctly that the

Mitchells' fraud and misrepresentation claims were preempted. *See, e.g., Michael,* 46 F.3d at 1331 (indicating that fraud claims would be preempted to the extent that they alleged fraudulent labeling); *see also* 21 U.S.C. § 360e(d)(2)(D) (requiring FDA to deny premarket approval of labeling that is "false or misleading in any particular").

On appeal, the Mitchells now have characterized their claim as one alleging that Collagen's "advertising and promotional materials" were fraudulent. *See* Reply Br. at 3. This belated refinement of their claim seeks to benefit from the Third Circuit's decision in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971), which held that fraudulent advertising claims were not preempted under the MDA. The Third Circuit reasoned that there were no requirements in the MDA that governed the promotional materials at issue in the case. Consequently, the court held that a state law fraud claim would not add any requirement "different from, or in addition to," a requirement under the MDA. *See id.* at 1330.

Even were we to give the Mitchells the benefit of the doubt and construe their claim with the specificity they have added on appeal, their claim nonetheless would fail. Unlike the defendant in *Michael*, Collagen, through the exhibits attached to the affidavit of Ross Erickson, established that the FDA had placed restrictions on Collagen's

advertising and promotional materials.[10] The Mitchells did not introduce affidavits, depositions, or other materials either to rebut Collagen's submissions or to demonstrate that there were genuine issues with respect to other promotional materials. Accordingly, summary judgment was proper even if the Mitchells' claim could be construed as applying to fraud and misrepresentation with respect to Collagen's advertising and promotional materials. *See* R.R. Donnelley & Sons Co., 42 F.3d at 443; *see also Meredith v. Allsteel, Inc.*, 11 F.3d 1354, 1358 (7th Cir. 1993) ("We may affirm the district court's grant of summary judgment on an alternative basis, as long as that basis finds support in the record.").

d. Warranty

The Mitchells' complaint raised the following warranty claim: "At all material times, Defendant, Collagen Corporation . . . warranted and represented to Plaintiff, Barbara Mitchell, that [Zyderm was] safe for [its] intended use and purpose." R.1, Ex.A at 2, Count I, ¶ 5. Before the district court, the Mitchells neither specified

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[10] *See, e.g.*, R.6, Ex.13 at 2 (Dec. 1981 letter from Acting Director of FDA Bureau of Medical Devices approving supplemental premarket application and indicating that "[n]o advertisement for this device shall recommend or imply that the device may be used for any use that is not mentioned in the approved labeling for the device. All written promotional material shall state the indications, contraindications, warnings, precautions and adverse effects of the device"); R.6, Ex.26 (Nov.1983 letter ordering Collagen to "refrain from any reference to 'FDA approval' or 'marketing clearance by the FDA' in all promotional material or labeling for Zyderm").

what warranties were at issue nor what statements of warranty Collagen allegedly provided.

i. Implied Warranty

Various circuits have held that implied warranty claims are preempted with respect to devices that have undergone the PMA process.[11] These courts have emphasized that such claims, as they relate to manufacturing or design problems, "by necessity depend[ ] upon the accepted standards for the design and manufacture of products" in the state whose law provides the cause of action – standards that "may deviate from the FDA's determinations in the PMA process or from the FDA's 'good manufacturing practices.' " *Michael*, 46 F.3d at 1325; *see also Mendes*, 18 F.3d at 19. Likewise, claims based upon inadequate warnings seek to add requirements "different from, or in addition to," the labeling approved by the

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[11] *See, e.g., Michael*, 46 F.3d at 1324-25; *Martello v. Ciba Vision Corp.*, 42 F.3d at 1168-69; *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.) (op. of Torruella, J., joined by Aldrich and Campbell, JJ.), *cert. denied*, 114 S. Ct. 84 (1993); *see also Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *6 (1st Cir. Aug. 14, 1995) (adopting analysis of district court, which held implied warranty claim preempted); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18-19 (1st Cir. 1994) (finding implied warranty claim preempted for Class III device not subject to PMA process); *Duncan v. Iolab Corp.*, 12 F.3d 194, 195 (11th Cir. 1994) (per curiam) (same for intraocular lens); *cf. Feldt v. Mentor Corp.*, 61 F.3d 431, 437 & n. 9 (5th Cir. 1995) (holding that implied warranty claim relating to defective design was not preempted with respect to Class III device that had not undergone PMA process and distinguishing *Michael* on the ground that the device at issue in *Michael* had undergone the PMA process).

FDA. *Mendes*, 18 F.3d at 18. In sum, "[a]s an implied warranty is a requirement upon a product that arises exclusively from the operation of state contract law, [implied warranty] claim[s] [are] preempted expressly by the MDA." *King*, 983 F.2d at 1135 (op. of Torruella, J., joined by Aldrich and Campbell, JJ.). We agree with the analysis of these other circuits, and therefore hold that the Mitchells' claim is preempted to the extent it alleges violation of an implied warranty relating to the design, manufacturing, or labeling of Zyderm.

ii. Express Warranty

As the Mitchells note on appeal, there is significant authority for the proposition that express warranty claims are not preempted by the MDA. The Third Circuit stated in *Michael v. Shiley, Inc.*, that

> [e]xpress warranties arise from the representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law. . . . The parties to a contract, not the state, define the substantive obligations of the contract and hence any express warranties. While the state provides for the enforcement of the parties' bargain, it does not define each party's duties.

46 F.3d at 1325. The court went on to note that its reasoning comported with the Supreme Court's recent decision in *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995). In *Wolens*, the Court considered the scope of the preemption provision in the Airline Deregulation Act of 1978, which provided, in pertinent part:

> [N]o State . . . shall enact or enforce any law, rule, regulation, standard, or other provision having the force and effect of law relating to rates, routes, or services of any air carrier.

See 115 S. Ct. at 821 (quoting 49 U.S.C. § 1305(a)(1)). The Court concluded that the statute did not preempt suits "seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings." *Id.* at 824. Focusing upon the phrase "enact or enforce" in the statutory scheme, the Court emphasized that "terms and conditions airlines offer and passengers accept are privately ordered obligations and thus do not amount to a State's 'enact[ment] or enforce[ment] [of] any law[.]' " *Id.* (internal quotation and citation omitted) (citing *Cipollone*, 112 S. Ct. at 2608 (plurality op.) ("[A] common law remedy for a contractual commitment voluntarily undertaken should not be regarded as a 'requirement imposed under State law[.]' "). The Court in *Wolens* concluded, "[a] remedy confined to a contract's terms simply holds parties to their agreements[.]" 115 S. Ct. at 824.

The operative phrase in the preemption provision at issue in *Wolens*, "enact and enforce," differs from the MDA's command that states may not "establish or continue in effect" any requirements different from or in addition to those set forth in the MDA. *Compare* 49 U.S.C. § 1305(a)(1) *with* 21 U.S.C. § 360k(a). Nevertheless, the reasoning in *Michael* does find significant support both in *Wolens* and in the portion of *Cipollone* quoted above. Moreover, we note that the Third Circuit also reasoned that, with respect to the MDA in particular, enforcement of an express warranty would not seek to add requirements "different from, or in addition to," those set forth

in the MDA, but rather, would "enforce the very language which the FDA approved" on the particular label at issue. *See* 46 F.3d at 1328. We agree.

Collagen seeks to counter the persuasiveness of *Michael* by noting that other circuits disagree. Collagen principally cites the First Circuit's decision in *King*. However, although Judge Torruella's separate opinion in *King* supports Collagen's argument that express warranty claims are preempted, *see* 983 F.2d at 1135 (op. of Torruella, J.), a majority in *King* declined to address the express warranty issue and suggested that "[e]xpress warranty might have created a problem for the defense of preemption." *Id.* at 1137 & n. 3 (Aldrich and Campbell, JJ., concurring) (citing *Cipollone*, 112 S. Ct. at 2622-23). Thus, contrary to Collagen's submission, King may not stand for the proposition that express warranty claims are preempted under the MDA; in turn, those decisions cited by Collagen that rely upon *King* for this proposition without additional analysis are not persuasive. *See, e.g., Martello*, 42 F.3d at 1169. *But see Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *6 (1st Cir. Aug. 14, 1995) (Campbell, J.) (affirming district court's dismissal of express warranty claim and stating that the Third Circuit's express warranty analysis in *Michael* "appears to be inconsistent with this circuit's approach as set forth in *King*, 983 F.2d at 1135," but not commenting on footnote 3 of Judge Aldrich's opinion in *King*). Accordingly, we hold, consistent with *Michael*, that the MDA does not preempt express warranty claims.

Once again, however, the Mitchells' summary judgment filings prevent them from benefitting from this

analysis. As we noted above, the Mitchells never specified in the district court whether their claim was based upon implied or express warranties. Likewise, the Mitchells never pointed to any express warranty that Collagen allegedly violated. In response to Collagen's submission that there was no genuine issue of material fact with respect to their complaint against Collagen, the Mitchells introduced no affidavits, depositions, documents, or other evidence creating a genuine issue of fact as to the existence of any express warranty provided by Collagen. Accordingly, we must hold that the Mitchells failed to meet their burden at the summary judgment stage and that, to the extent they raised an express warranty claim in their complaint, summary judgment was proper even though such claims are not preempted by the MDA. *See R.R. Donnelley & Sons Co.*, 42 F.3d at 443; *see also Meredith*, 11 F.3d at 1358 ("We may affirm the district court's grant of summary judgment on an alternative basis, as long as that basis finds support in the record.").

Conclusion

For the foregoing reasons, the decision of the district court is affirmed.

AFFIRMED

A true Copy:
Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit

UNITED STATES COURT OF APPEALS

For the Seventh Circuit
Chicago, Illinois 60604

November 22, 1995.

Before

Hon. RICHARD D. CUDAHY, Circuit Judge

Hon. KENNETH F. RIPPLE, Circuit Judge

Hon. MICHAEL S. KANNE, Circuit Judge

BARBARA MITCHELL and GREGORY MITCHELL, Plaintiffs-Appellants,	]	Appeal from the United States District Court for the Northern District of Indiana, Hammond Division.
No. 94-3946	v.	No. 93 C 283.
COLLAGEN CORPORATION, Defendant-Appellee.	]	James T. Moody, Judge.

ORDER

On consideration of the petition for rehearing filed by plaintiffs-appellants on October 16, 1995, all the judges on the original panel have voted to deny the petition. Accordingly,

IT IS ORDERED that the petition for rehearing be, and the same is hereby, DENIED.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

BARBARA and GREGORY MITCHELL	)	
Plaintiffs,	)	**No. 2:93 cv 283**
v.	)	
COLLAGEN CORPORATION,	)	
Defendant	)	

ORDER and MEMORANDUM OPINION

(Filed Nov. 07, 1994)

This is a diversity action in which plaintiffs, the Mitchells, allege that Barbara Mitchell was injured by injections of collagen compounds, Zyderm and Zyplast, manufactured by defendant Collagen Corporation ("Collagen"). The Mitchells seek recovery under several alternative Indiana tort law theories. Before the court for decision is a motion for summary judgment filed by Collagen, and two motions filed by the Mitchells seeking to amend their complaint.

Motions to Amend Complaint

In both motions the Mitchells seek to add to their complaint a claim that Collagen has violated provisions of the Indiana Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-1 *et seq.* A brief summary of the posture of the case provides helpful context for discussion of the motions.

The Mitchells' complaint against collagen was filed in state court on January 21, 1993. Collagen then removed the case to this court, and, on December 30, 1993, moved for summary judgment. Collagen asserts that all state law tort theories raised by the Mitchells' complaint are preempted by federal law.

On January 25, 1994, before responding to the summary judgment motion, the Mitchells moved for leave to amend their complaint to add the Deceptive Consumer Sales Act claim. The Mitchells contend that this claim is not preempted, even if all of their other claims are. Collagen immediately objected that the amendment would be futile, the amended complaint on its face showing the Deceptive Consumer Sales Act claim to be barred by the statute of limitations.

On February 17, 1994, the Mitchells filed their second motion to amend, an "amended" motion for leave to file an amended complaint. The purpose of the amended motion was to modify paragraph four of the proposed amended complaint to add the bracketed and italicized portion of the following quotation: "Plaintiffs were not reasonably able to discover or learn that there was a relationship between Defendant COLLAGEN CORPORATION'S products and her injuries until late 1991 [*, and due to the fraud and concealment of her causes of action by Collagen Corporation*]." The Mitchells explained that the purpose of this amendment was to make the amended complaint read as "more clearly setting out such fraud and/or fraudulent concealment on the part of Collagen

Corporation, which tolls the statute of limitations under the [Deceptive Consumer Sales] Act."[1]

Under Rule 15(a) of the FEDERAL RULES OF CIVIL PROCEDURE, the court must freely allow a complaint to be amended "when justice so required." FED.R.CIV.P. 15(a); *DeSalle v. Wright*, 969 F.2d 273, 277-78 (7th Cir. 1992). It would be oxymoronic to suggest that justice "requires" that an amendment be allowed when the amendment would be futile. Thus, despite the liberality required by Rule 15(a), it is not an abuse of discretion to deny leave to make a futile amendment. *Id.* When the proposed amendment could not withstand a motion to dismiss, denying leave saves the defendant and the court needless work. *Perkins v. Silverstein*, 939 F.2d 463, 472 (7th Cir. 1991).

The Indiana Deceptive Consumer Sales Act contains a two-year occurrence statute of limitations: "Any action brought under this chapter may not be brought more than two years after the occurrence of the deceptive act. . . . " Ind. Code. § 24-5-.5-5(b). Because the statute unambiguously commences the limitations period on an "occurrence" rather than "accrual" of the cause of action, the period runs from that occurrence regardless whether the resultant damage can be ascertained. *See Havens v. Ritchey*, 582 N.E.2d 792, 794 (Ind. 1991) (construing similar statute of limitations in Indiana Medical Malpractice Act); *Weinberg v. Bess*, 638 N.E.2d 841, 844 (Ind. Ct. App.

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[1] The quoted language is from "Plaintiff's Reply to Defendant's Objection to Motion for Leave to File Amended Pleading," filed on February 17, 1994. This document was stricken on Collagen's motion because untimely under this District's Local Rules.

1994) (for medical malpractice, "two-year period begins to run at the occurrence of the negligence rather than at the time the negligence is discovered").

Thus, the statute of limitations began to run in the present case, at the latest, on September 22, 1988, when Barbara Mitchell received her last injection – her last "purchase" of Collagen's product – not in late 1991 at the time she alleges she discovered that her injuries were related to the product. The two-year statute thus expired September 22, 1990, making her complaint filed January 21, 1993, appear untimely. It is this untimeliness that makes the Mitchells' attempt to add an allegation of fraudulent concealment important.

The statute of limitations in the Deceptive Consumer Sales Act is subject to the equitable doctrine of fraudulent concealment, which estops a defendant who has actively deceived a plaintiff from asserting the defense.[2] *Cwiakala v. Economy Autos, Ltd.*, 587 F. Supp. 1462, 1466 (N.D. Ind. 1984). Thus, taking the allegations of the Mitchells' proposed amended complaint as true, Collagen's fraudulent concealment tolled the running of the two-year statute until late 1991 when the Mitchells learned of Collagen's (alleged) responsibility for her injuries.

The tolling of the limitations period until that time, however, did not allow the Mitchells a fresh two-year period in which to file their complaint. Instead, because "[e]quity supplies what equity requires," their cause of

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[2] When a fiduciary or confidential relationship exists, passive failure to disclose will suffice. *Hughes v. Glaese*, 637 N.E.2d 822, 825 (Ind. Ct. App. 1994).

action had to be commenced within a reasonable time. *Cacdac v. Hiland*, 561 N.E.2d 758, 759 (Ind. 1990) (medical malpractice); *O'Neal v. Throop*, 590 N.E.2d 984, 988 (Ind. Ct. App. 1992) ("two-year statute of limitations does not apply under the doctrine of fraudulent concealment . . . Instead, a plaintiff claiming fraudulent concealment has a duty to bring the action within a reasonable time after discovering the malpractice.")

Because malpractice actions are (or at least are perceived to be) relatively common and an injury from malpractice often becomes apparent only later, the determination whether a plaintiff relying on fraudulent concealment to toll the limitations period has commenced his/her action in a reasonable time comes up there often. The following periods of delay have been held unreasonable as a matter of law: twenty-two months, *Cacdac*, 561 N.E.2d at 759 ("delay of twenty-two months . . . was not reasonable . . . trial court should have granted Dr. Cacdac summary judgment"); thirteen months, *Babcock v. Lafayette Home Hospital*, 587 N.E.2d 1320, 1324-25 (Ind. Ct. App. 1992); twenty-one months, *Yarnell v. Hurley*, 572 N.E.2d 1312, 1315 (Ind. Ct. App. 1991); twenty-two months, *Cyrus v. Nero*, 546 N.E.2d 328, 331 (Ind. Ct. App. 1989); seventeen months, *Basinger v. Sullivan*, 540 N.E.2d 91, 95 (Ind. Ct. App. 1989); twenty-two months, *Spoljaric v. Pangan*, 466 N.E.2d 37, 45 (Ind. Ct. App. 1984).

In the present case the Mitchells have pleaded that they became aware of the linkage between Collagen's product and Barbara Mitchell's injuries late in 1991. Even though they filed a complaint approximately thirteen months later in January, 1993, they waited twelve more months, until January, 1994, before trying to bring their

Deceptive Consumer Sales Act claim, *i.e.*, at least twenty-five months after discovering the connection to Collagen. This twenty-five month delay was unreasonable. Even if it could be argued that the January, 1994, proposed amendment should "relate back" – an argument that the court finds unappealing – to the January, 1993, filing, making the delay only thirteen months, even that delay would be unreasonable. Thus, because it is clear that the Mitchells' Deceptive Consumer Sales Act claim is barred by the statute of limitations, their attempt to add that claim to their complaint is futile, and both of their motions for leave to amend their complaint are DENIED.[3]

Collagen's Motion for Summary Judgment

Collagen contends that all of the state law causes of action the Mitchells assert are preempted by federal law, thereby entitling Collagen to a judgment of dismissal with prejudice. Alternatively, Collagen contends that as to any claims which are not preempted, the Mitchells have rested on their complaint and have no evidence in support of such claims, entitling Collagen to summary judgment.

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[3] The Mitchells have not argued that Ind. Code § 34-1-2-9 (statutory extension of statute of limitations for fraudulent concealment) applies to commence a new two-year period beginning in late 1991, so the court need not decide that issue. In *Guy v. Schuldt*, 138 N.E.2d 891, 893 (Ind. 1956), the Indian Supreme Court ruled that § 34-1-2-9 did not provide an exception to the later-enacted special statute of limitations for medical malpractice actions. Giving that decision a hasty look, the Court's reasoning seems equally applicable here.

Zyderm and Zyplast are classified by the Food and Drug Administration ("FDA") as "Class III medical devices" extensively regulated under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-395, more specifically, pursuant to the Medical Device Amendments of 1976 ("MDA") thereto, 21 U.S.C. §§ 360c-360l. As explained in both *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, ___ U.S. ___, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993), and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, ___ U.S. ___, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993), the MDA requires that medical devices undergo a rigorous premarket approval ("PMA") process to ensure their safety and efficacy before they can be dispensed to the public.

The MDA prohibits states from subjecting a medical device to "any requirement (1) which is different from, or in addition to, any requirement applicable under the [Food, Drug and Cosmetic Act] to the device, and (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under" the Act. 21 U.S.C. § 360k(a). In *Stamps* and *King* the Fifth and Fourth Circuits have agreed with Collagen's stance that this provision preempts state tort claims like those the Mitchells have pleaded. The Mitchells respond that both decisions are "patently incorrect" and should not be followed by this court.

There is both a short and long answer to the preemption question debated by the parties. The short answer is that the court agrees with the result reached in *Stamps* and *King*. In § 360k(a) Congress expressly defined the

preemptive reach of the MDA, so courts need only identify the domain created by the statutory language.[4] *Cipollone v. Liggett Group, Inc.*, ___ U.S. ___, 112 S.Ct. 2608, 2618, 120 L.Ed.2d 407 (1992); *American Agriculture Movement v. Board of Trade*, 977 F.2d 1147, 1154 (7th Cir. 1992). *Stamps* and *King* correctly conclude that Congress, by using the phrase "any requirement," meant for the preemption provision to "sweep broadly" precluding not only positive enactments but also common-law tort actions.[5] *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370 (7th Cir. 1993) (*Cipollone* "held that sweeping Congressional efforts to pre-empt state regulation also bar state damages claims"); *Stamps*, 984 F.2d at 1421; *King*, 983 F.2d at 1134-35. The Court of Appeals explains:

> If the FDA in a valid regulation under the Medical Device Amendments requires X, and X relates to safety or effectiveness, a state cannot, whether through statute, regulation, or common law decision, require non-X or X ± Y.

Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir.), *cert. denied*, ___ U.S. ___, 113 S.Ct. 327, 121 L.Ed.2d 246 (1992).

The PMA process – the validity of which the Mitchells do not question – is without doubt an FDA regulation of this nature: a medical device categorized as a

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[4] Justices Blackmun, Kennedy and Souter concurring in Section IV of the plurality opinion result in a majority for this proposition. *Vango Media, Inc. v. New York City*, 34 F.3d 68 (2d Cir. 1994).

[5] The FDA is of the same view, declaring that preemption applies equally to "statute, ordinance, regulation, or court decision." 21 C.F.R. § 808.1(b).

Class III device is subject "to premarket approval to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). As the Mitchells admit in opposing summary judgment, this requirement is not substantially different from "state tort products liability and similar actions requiring reasonable product safety and effectiveness." Plaintiffs' Brief, p. 10.[6] These state tort actions are therefore requirements in addition to the PMA process, and preempted. *Stamps*, 984 F.2d at 1423-24. "The plaintiff wishes in the name of state tort law to impose additional requirements . . . and this engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Device Amendments." *Slater*, 961 F.2d at 1333. Effectively, the MDA causes blanket preemption.[7]

This short answer is less than completely satisfactory. It does not explain why the court rejects the Mitchells' arguments that *Stamps* and *King* were wrongly decided. It also does not explain why the court, unlike *Stamps*[8] and

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[6] All references to "Plaintiffs' Brief" are to "Plaintiffs' Response in Opposition to Defendant's Motion for Summary Judgment and Memorandum of Authorities," filed January 28, 1994.

[7] *Ministry of Health v. Shiley, Inc.*, 858 F.Supp. 1426, 1437 (C.D. Cal. 1994) concludes that "the First and Fifth Circuits, and numerous district courts, with one exception, have followed a rule of blanket preemption [under the MDA] for Class III devices." The court lists the cases it surveyed to reach this conclusion. 858 F.Supp. 1437 n. 17. *Shiley*, reaching a different result, appears to become the second exception. As discussed *infra* at p. 23 n. 18, the court respectfully disagrees with *Shiley*.

[8] *Stamps* does not categorically analyze each cause, but only because it relies on a prior decision, *Moore v. Kimberly-Clark*

King, has not followed the approach recommended by the *Cipollone* plurality, inquiring tort-by-tort whether the tort's underlying duty relates to safety and effectiveness. 112 S.Ct. at 2621. The court therefore will address each of the Mitchells' arguments, and in so doing, attempt to explain where it parts company with *Stamps* and *King*. The arguments are addressed in the order made in the Plaintiffs' Brief.[9]

1. Initial Preemption Determination

First, the Mitchells argue that the MDA does not preempt state law unless the FDA first determines that the particular state law requirement in question is preempted. Because the MDA preempts only state law requirements which are "different from, or in addition to" federal requirements,[10] 21 U.S.C. § 360k(a), the Mitchells believe the following (as misquoted by them) portion of

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Corp., 867 F.2d 243 (5th Cir. 1963), which did. *Stamps*, 984 F.2d at 1422.

[9] Because the court has denied the Mitchells' request to amend their complaint to add a cause of action under the Indiana Deceptive Consumer Sales Act, the court does not address their arguments that this cause would not be preempted.

[10] This is a fine example of drafting overkill making a statute less than clear. If only different or additional requirements are preempted, then only identical requirements are not preempted (because lesser requirements would be preempted as different). Does it matter one whit that identical requirements are not preempted? It would seem that where state and federal requirements are identical, compliance with either would satisfy both, making the preemption issue irrelevant.

21 C.F.R. § 808.1(e) sets out a prerequisite to preemption: "It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, such requirements. . . . " The Mitchells believe that until the FDA makes this determination after being requested by an "interested person" to issue an advisory opinion as to preemption pursuant to 21 C.F.R. § 808.5(a), the MDA has no preemptive effect and a court ruling otherwise would "usurp the FDA's authority." Plaintiffs' Brief, p. 4.

This argument is untenable, and can be made only by divorcing the misquoted regulation from its context. The MDA allows states and their governmental units to apply to the FDA for exemption of state law from preemption. 21 U.S.C. § 360k(b). Accordingly, the FDA has promulgated regulations "for the submission, review, and approval of applications for exemption from Federal preemption. . . . " 21 C.F.R. § 808.1(a). It is only in the context of these regulations that the FDA has a responsibility to determine whether state requirements differ from federal requirements: this determination, rather than being a prerequisite to preemption, is necessary only because the statute itself preempts different or additional state requirements.

This is clear not only from viewing § 808 as a whole but merely from reading the complete text of § 808.1(e), as opposed to the sentence fragment (mis)quoted by the Mitchells:

> It is the responsibility of the Food and Drug Administration, subject to review by Federal Courts, to determine whether a State or local

> requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any state or political subdivision whose requirements relating to devices are preempted by section [360k(a)] may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(Emphasis added). It is plain that § 360k(a) of the MDA causes immediate preemption whenever state and federal requirements are inconsistent, otherwise, there would be no initial burden on the states to decide whether to seek an exemption.

Thus, the procedure for obtaining an advisory opinion, rather than being the catalyst for preemption, allows an "interested person" to determine whether a state requirement can safely be ignored, and a state to determine whether its requirements are enforceable or there is a need to seek an exemption from preemption. This interpretation makes sense of the following aspect of the procedure for obtaining an advisory opinion: "The [FDA] . . . after consultation with the State or political subdivision, may treat a request by a State or political subdivision for an advisory opinion as an application for exemption from preemption under § 808.20." This provision presupposes that the MDA causes preemption to occur before an advisory opinion is obtained. Were it

otherwise, as the Mitchells argue, a state could not benefit by requesting an advisory opinion, but instead only suffer the undesired consequence – preemption of a state regulation.

2. *FDA Opinions that General State Tort Law not Preempted*

The Mitchells' second argument is that the FDA has already determined that the MDA preempts only state tort law requirements directed specifically at medical devices, not tort law of general applicability. The Mitchells have attached what appear[11] to be copies of two FDA advisory opinions, dated March 8, 1984, and February 2, 1988, which take that position. The 1988 letter states in part that "it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 360(k)) preempts only state and local requirements that are specifically related to medical devices." Citing *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985), the Mitchells argue that the FDA's position is dispositive.

This is simply not true, and the Mitchells ignore that part of their cited authority that contradicts their position. In *Hillsborough County* the Supreme Court did not, as the Mitchells' citation suggests, hold that an agency determination is dispositive. Instead, the Court stated "[t]he FDA's statement is dispositive . . . unless . . . the agency's position is inconsistent with clearly expressed

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[11] Collagen has not objected to the documents' authenticity.

congressional intent. . . . " *Hillsborough Cuonty,* 471 U.S. at 714, 105 S.Ct. at 2376.

The FDA's interpretation that the MDA preempts only state requirements directed specifically at medical devices is contrary to the intent expressed in the statute, considering the Supreme Court's interpretation of similar language in other statute's preempting state law. The MDA preempts any state law which "relates to" safety and effectiveness. 21 U.S.C. § 360k(a). The Supreme Court has held that when Congress chooses "relating to" phraseology in a preemption provision, it intends the provision to sweep expansively. *Morales v. Trans World Airlines,* ___ U.S. ___, 112 S.Ct. 2031, 119 L.Ed.2d 157 (1992).

In *Morales* the Court rejected the cramped definition of "relating to" that the FDA has adopted in respect to the MDA:

> [P]etitioner advances the notion that only State laws specifically addressed to the airline industry are preempted, whereas the [Airline Deregulation Act] imposes no constraints on laws of general applicability. Besides creating an utterly irrational loophole . . . , this notion similarly ignores the sweep of the 'relating to' language. We have consistently rejected this precise argument in our ERISA cases: "[A] state law may 'relate to' a benefit plan, and thereby be preempted, even if the law is not specifically

> designed to affect such plans, or the effect is only indirect."

Morales, 112 S.Ct. at 2038 (citations omitted).

The "precise argument" rejected by the Supreme Court – that a law of general applicability does not "relate to" a specific subject area – is the position the FDA has taken in interpreting the MDA. Because such an interpretation is contrary to the clearly expressed intent of Congress, the court gives it no deference. *Dole v. United Steelworkers of America*, 494 U.S. 26, 42, 110 S.Ct. 929, 938, 108 L.Ed.2d 23 (1990).

3. The Indians Attorney General Opposes MDA Preemption

The Mitchells' third argument is that Pamela Carter, Indiana's Attorney General, has publicly opposed preemption of state tort law by the MDA, when Indiana joined in an *amici curiae* brief seeking *certiorari* in *Stamps* and *King*. The Mitchells ask the court to consider the arguments made in the *amici curiae* brief.

Preemption doctrine results from the dual between sovereigns inherent in a federal system. Whether a statute Congress enacts preempts state law depends on Congress' intent as expressed in the statute, not on whether a state agrees that its laws are, or should be, preempted. For this reason, and because the court does not sanction the practice of adopting by reference briefs from other cases, this argument does not merit further discussion.

4. *Proposed Legislation Shows the MDA did not Preempt State Law*

The Mitchells' fourth argument is that Congress does not view the MDA as having preempted state tort law. Proposed legislation introduced October 13, 1993, "The Comprehensive Family Health Access and Savings Act," contained a provision prohibiting an award of punitive damages against the manufacturer of a medical device. As this provision would be unnecessary if the MDA preempts state tort law, the Mitchells' argument is not implausible. As proposed legislation, however, this at best demonstrates the understanding of the act's sponsors, not Congress. Even given broader due, as the plurality noted in *Cipollone* "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *United States v. Price*, 361 U.S. 304, 313, 80 S.Ct. 326, 332, 4 L.Ed.2d 334 (1960); *Cipollone*, 112 S.Ct. at 2619.

Most important, in *Cipollone* the Court held that an express preemption provision in a statute confines judicial determination of the statute's preemptive reach to construction of that provision. 112 S.Ct. at 2618; see also *N.A.A.C.P. v. American Family Mutual Insurance Co.*, 978 F.2d 287, 294 (7th Cir. 1992) ("We must determine what Congress meant by what it enacted, not what Senators and Representatives said, thought, wished or hoped.") As a result, it would be improper for this court to interpret § 160k(a) of the MDA by divining legislative intent from the provisions of unenacted legislation considered by a subsequent Congress.

5. The MDA Does Not Preempt General State Tort Law

Fifth, the Mitchells contend that state court laws of general applicability (i.e., not applicable only to medical devices) are not preempted. They first point to 21 C.F.R. § 808.1(d)(1) which states exactly this proposition: "Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes and the Uniform Commercial Code (warranty of fitness)) . . . ".

This is a retread of their second argument, which relied on FDA advisory opinions to make the point, but with different evidence of how the FDA interprets the statute. Thus, the court need only reiterate that this interpretation is contrary to the Congress' intent, as expressed in the § 360k(a) of the MDA, and so the FDA regulation is entitled to no deference.[12] *Dole*, 494 U.S. at 42, 110 S.Ct. at 938.

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[12] The FDA's conclusion that requirements of general applicability are not preempted appears to derive from its view that such requirements "are not preempted by section 521(a) [§ 360k(a)] because they are not 'requirements applicable to a device' within the meaning of section 521(a) of the act. . . . " 21 C.F.R. § 808.1(d). Oddly, § 360k(a) does not contain the phrase the FDA places in quotation marks.

Instead, the word "applicable" appears only in the following context: " . . . no State . . . may establish or continue in effect with respect to a device. . . . any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device . . . " 21 U.S.C. § 360k(a) (emphasis added.) The phrase "with respect to a device" appears to limit preemption only by meaning that state

Continuing with additional support for the proposition that general tort laws are not preempted, the Mitchells argue that preemption occurs only after the FDA establishes "specific counterpart regulations . . . making any existent divergent state or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements." 21 C.F.R. § 808.1(d). The Mitchells insist that there are no FDA regulations applicable to Zyderm and Zyplast which are "specific counterpart regulations" to state tort law. In other words, the federal PMA process would preempt only a similar state PMA process. The Mitchells rely on *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 1, 837 P.2d 1273 (1992), which held that the PMA process is a mere procedural requirement, not a regulation of safety and effectiveness, and thus does not trigger preemption.

That view does not find support in this circuit, however. Considering the preemptive effect of procedural, as opposed to substantive, MDA requirements for experimental devices, the Court of Appeals observed that such regulations "specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect." *Slater*, 961 F.2d at 1333. Similarly, the PMA process, while procedural, is designed to require manufacturers of medical devices to determine and demonstrate that the devices are safe and effective before obtaining approval to market. The court therefore agrees with *Stamps* that once the

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requirements are not voided: they continue in effect insofar as they apply to anything other than medical devices.

FDA imposes any requirement upon a device – PMA being a requirement – state tort causes of action relating to safety and effectiveness are preempted.[13] *Stamps*, 984 F.2d at 1423-24.

The Mitchells' final effort to support their "no preemption of general law" argument is based on the FDA's construction of the phrase "different from, or in addition to" used in § 360k(a) of the MDA. The FDA sensibly believes this phrase as meaning that state requirements that are "substantially identical to" federal requirements are not preempted. 21 C.F.R. § 808.1(d)(2). In an attempt to attach meaning to this irrelevancy, see n. 10 at p. 10, *supra*, the FDA defines "substantially identical to" to include any state requirement that "does not significantly differ in effect from a Federal requirement." 21 C.F.R. § 808.3. It is not difficult to conclude then, as the Mitchells do, that state tort laws are not preempted because they do not differ "in effect" from the PMA – both having the effect of requiring medical devices to be safe and effective.

The Mitchells' analysis is sound: the FDA's definition of "substantially identical to" is not. The plain language of the MDA preempts additional or different state requirements relating to safety and effectiveness, whether or not they have the same "effect" as the federal requirements. For example, 21 C.F.R. § 801.430(f) specifies the absorbency test to be used for menstrual tampons. A state

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[13] *Stamps* also points out that *Larsen* is distinguishable because it involved a "substantially equivalent" device which underwent a less rigorous PMA than a new device. *Stamps*, 984 F.2d at 1423 n. 6.

law requiring a different test but with the same effect – determining absorbency – would nevertheless be preempted.[14]

And so it is with state tort laws. While they may have the same effect as the PMA process, safety and effectiveness, they achieve that effect only by imposing different or additional requirements on devices: *e.g.*, different or additional premarket testing should have been done, the device literature should have contained additional or different warnings. "[T]his engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Device Amendments." *Slater*, 961 F.2d at 1333.

6. Plaintiffs' Claims not Preempted Under Cipollone Analysis[15]

The Mitchells argue that applying the preemption analysis used by the Supreme Court in *Cipollone*, the MDA does not preempt their breach of warranty, fraud and misrepresentation claims. *Stamps* and *King*, both coming to a contrary conclusion, are accordingly erroneous and should not be followed. In order to address

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[14] Making this point further, a manufacturer can use a different absorbency test only by demonstrating equivalency and obtaining FDA approval. 21 C.F.R. § 801.430(f)(3).

[15] In the first portion of this argument plaintiffs reiterate for the third time that 21 C.F.R. § 808.1(d)(1) excludes tort laws of general applicability from preemption. In addressing plaintiffs' second and fifth arguments the court has explained why it rejects that FDA interpretation of the MDA's preemptive scope.

this argument the court first explains its understanding of the badly fractured decision in *Cipollone*, and the adherence of *Stamps* and *King* thereto.

In *Cipollone* the Court addressed the issue of the scope of preemption under the Public Health Cigarette Smoking Act of 1969, which preempts any "requirement or prohibition based on smoking and health . . . imposed under State law . . . ". 15 U.S.C. § 1334(b). While six of the nine Justices agreed that a "requirement or prohibition" includes state common law tort causes, no majority agreed on how to determine whether a tort requirement is "based on smoking and health."[16]

A plurality of four Justices decided that the answer depends on whether the "legal duty that is the predicate of the common law damages action" is "based on" smoking and health. 112 S.Ct. at 2621. Thus, the plurality concluded that a fraud claim based on advertisements containing false statements of fact would not be preempted because "not predicated on a duty 'based on smoking and health' but rather on a more general obligation – the duty not to deceive." *Cipollone*, 112 S.Ct. at 2624. On the other hand, failure-to-warn claims (related to advertising and promotion) were held preempted, and

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[16] Prior to amendment in 1969, instead of "based on" the statute used the phrase "relating to smoking and health" – very similar to the MDA's "relates to the safety and effectiveness." In commenting on the effect of Congress having amended the wording, the plurality observed that "the phrase 'relating to smoking and health' . . . was essentially unchanged by the 1969 Act . . . ". *Cipollone*, 112 S.Ct. at 2624.

thus implicitly found to be based on smoking and health. *Id.* at 2621-22.

Justice Blackmun, joined by Justices Kennedy and Souter, of the view that the statute did not preempt state common-law damages actions at all, dissented from the plurality's "little short of baffling" conclusion that some common-law tort causes of action were preempted, and thus from the court's judgment to that extent.[17] *Id.* at 2627, 2631. Moreover, in dissenting the Justices took the plurality to task for focusing its analysis on the legal duty serving as the predicate of the tort. Justice Blackmun found the analysis' "most obvious problem . . . its frequent shift in the level of generality at which it examines individual claims." *Id.* at 2631.

As an example of this shift, Justice Blackmun pointed to the plurality's conclusion that failure to warn claims were preempted, but fraudulent misrepresentation claims were not, because based on a general duty not to deceive. Justice Blackmun objected that the failure-to-warn claims "could just as easily be described as based on a 'more general obligation' to inform consumers of known risks" and thus found not preempted. Justice Blackmun viewed

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[17] The Justices concurred with the plurality's opinion to form a majority for the following propositions: 1) the preemptive scope of a statute must be determined entirely from the express language used in its preemption provisions, *Id.* at 2625; 2) state common-law damages claims are not preempted unless the statutory language chosen by Congress indicates a clear and manifest purpose to do so, *Id.* at 2626, and 3) the 1965 Federal Cigarette Labeling and Advertising Act does not preempt state common-law damages claims. *Id.*

the plurality's approach as creating "a crazy quilt of preemption," concluding:

> In short, I can perceive no principled basis for many of the Court's asserted distinctions among the common-law claims, and I cannot believe that Congress intended to create such a hodgepodge of allowed and disallowed claims. . . . I can only speculate as to the difficulty lower courts will encounter in attempting to implement the Court's decision.

Id. at 2631.

Justice Scalia, joined by Justice Thomas, agreed with Justice Blackmun's critique of the plurality's approach, describing it as "suspect, to begin with, because the plurality is unwilling to apply it consistently." *Id.* at 2636. Justice Scalia proposed an alternative: "Once one is forced to select a *consistent* methodology for evaluating whether a given legal duty is 'based on smoking and health', it becomes obvious that the methodology must focus not upon the ultimate source of the duty (*e.g.*, the common law) but upon its proximate application." *Id.* To apply this test, Justice Scalia "would ask . . . whether, whatever the source of the duty, it imposes an obligation in this case because of the effect of smoking upon health," and would have concluded in the case before the Court that all of the tort claims raised were preempted. *Id.* at 2637.

This effort to explain the Justices' diverging opinions is of more than pedantic interest: when no opinion commands the support of a majority of the Justices, the task of this court is to determine the court's holding by finding the narrowest ground upon which those concurring

with the plurality agree, i.e., the "lowest common denominator" holding. *Marks v. United States*, 430 U.S. 188, 193, 97 S.Ct. 990, 993, 51 L.Ed.2d 260 (1977); *Cygnar v. City of Chicago*, 865 F.2d 827, 838 (7th Cir. 1989); *Janowiak v. City of South Bend*, 836 F.2d 1034, 1041 (7th Cir. 1987); *Britton v. South Bend Community School Corp.*, 819 F.2d 766, 768 (7th Cir. 1987); *Schindler v. Clerk of Circuit Court*, 715 F.2d 341, 345 n. 5 (7th Cir. 1983).

While Justices Scalia's and Thomas' votes created a majority for the court's judgment that state law tort claims "based on smoking and health" were preempted, there is no narrow ground of agreement on the method for making that determination. To the contrary, as just explained above, a majority of five Justices agreed that the plurality's "ultimate source" analysis was flawed and unworkable. Thus, there is no lowest common denominator holding instructing lower courts how to determine when a tort requirement is "based on" or "relates to" something else – in this case, safety and effectiveness – and is preempted. Cf. *Schindler*, 715 F.2d at 345, n. 5.

Returning to the Mitchells' argument, they believe that if *Stamps* and *King* had faithfully followed *Cipollone*, the decisions would have found breach of warranty, fraud and misrepresentation claims not preempted by the MDA. The unacknowledged premise of this argument is that the *Cipollone* plurality's "ultimate source" analysis is a holding which must be followed.[18] That premise, which

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[18] This is the approach taken in what appears to be the most recent case addressing the scope of preemption under the MDA, *Ministry of Health v. Shiley*, 858 F.Supp. 1426 (C.D. Cal. 1994). *Shiley* concludes that *Cipollone* requires that "state claims

finds some support in *Stamps*, 984 F.2d at 1422, and, to a lesser degree, *King*, is both unfounded and suspect. As explained above, unfounded because the analysis is not a "least common denominator" agreed to by a majority of the Justices; suspect because, as *Stamps* and *King* both recognize, *Cipollone* does suggest that fraud and breach of warranty claims are not preempted.

Stamps and *King* both somewhat uncomfortably reach the opposite result, however. For example, in finding the fraud claims at issue preempted by the MDA, *Stamps* read the complaint as having pleaded fraud inadequately, instead sounding in negligence. *Stamps*, 984 F.2d at 1422 n. 5. *King* read the complaint's fraud claim as having been *originally* based on a statute requiring privity, despite plaintiff's insistence the claim (like that in *Cipollone*) was based on a general duty not to deceive. *King*, 983 F.2d at 1136.

Neither distinction is compellingly persuasive, particularly in this circuit where a "complaint need not identify a legal theory, and specifying an incorrect theory is not fatal." *Bartholet v. Reishauer A.G. (Zurich)*, 953 F.2d 1073, 1078 (7th Cir. 1992). The court believes that *Stamps* and *King* both reached a correct result, however, and one that can easily be supported simply by applying the

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against Class III device manufacturers survive if the legal duty underlying the state claim either has a basis independent of the MDA's focus on the medical device's safety and effectiveness, or arises from the manufacturer and not from the state." 858 F.Supp. at 1440. For the reasons explained in this order, the court respectfully disagrees with *Shiley*.

"proximate application" methodology proposed by Justice Scalia. 112 S.Ct. at 2636-37. Because the court does not read *Cipollone* as providing a holding that requires otherwise, and because the court believes it the better and more consistent of the two approaches, the court will apply the "proximate application" methodology to the Mitchells' tort causes of action.

To apply Justice Scalia's proximate application methodology in the present circumstances, the court simply inquires whether the tort imposes an obligation that relates to the safety and effectiveness of Zyderm and Zyplast, no matter where the source of the tort's duty lies. Considering this as the relevant inquiry with respect to each of the Mitchells' tort claims – at least those for which there is evidentiary support creating a factual dispute sufficient to withstand summary judgment – the court finds all preempted.

As to fraud and misrepresentation, the Mitchells' claim takes two avenues. First, that Collagen obtained the FDA's approval to market Zyderm and Zyplast through fraud and misrepresentation in the PMA process. Second, that Collagen continues to market the devices through fraud and misrepresentation.

As to fraud in the PMA process, the Mitchells' claims, even if not preempted, fail for lack of proof. The Mitchells have not disputed Collagen's evidence that the FDA has comprehensively reexamined its original decision to approve Collagen's PMA application and reaffirmed that decision. The Mitchells have merely rested on their pleadings, failing to come forward with any proof of the fraud

they allege. When opposing a motion for summary judgment, a party who has the burden of proof may not rest on the allegations of their pleadings.[19] *Chambers v. American Trans Air, Inc.*, 17 F.3d 998, 1002 (7th Cir. 1994).

Moreover, the evidentiary problem aside, this fraud claim would require the Mitchells to prove that more, or different, information should have been provided to the FDA as part of Collagen's PMA application, causing the FDA to reach a different decision. Thus the torts would impose additional obligations relating to safety and effectiveness and are preempted. *King*, 983 F.2d at 1136, 1140.

Similarly, with respect to the Mitchells' claims that Zyderm and Zyplast are marketed through fraud and misrepresentation, "[i]f the MDA does nothing else, it regulates the . . . sale and marketing of Class III medical devices in an extensive way. The MDA does this through the packaging and labeling requirements which directly affect the marketing and sale of the product." *King*, 983 F.2d at 1136. Thus, the Mitchells' claims with respect to fraud in advertising would impose additional requirements and are preempted.

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[19] After the briefing had closed on Collagen's motion for summary judgment, the Mitchells, for the first time, moved for a continuance in order to conduct discovery to support their response. This effort, made nearly two months after responding to Collagen's motion (after being allowed an extension of time to make that response), comes too late. The Mitchells chose to respond to the motion instead of utilizing RULE 56(f) to first obtain the discovery (allegedly) needed. As a result, the motion is ruled on as briefed. *Chambers*, 17 F.3d 1002.

As to breach of warranty claims, the court agrees with *King* that the MDA is not like the statute addressed in *Cipollone*, which did not restrict the ability of cigarette manufacturers to make warranties in their advertising and promotion. Instead, all aspects of product labeling and literature are regulated by the FDA under the MDA, preventing Collagen from making any warranties that are not FDA approved. *King*, 983 F.2d at 1135. Thus, a breach of warranty cause of action would impose different or additional requirements with respect to safety and efficiency, and is preempted.

As to their failure to warn and insufficient warning claims, the Mitchells contend (and Collagen admits) that under the MDA a device manufacturer can add additional safety warnings to product labels without prior FDA approval. 21 C.F.R. § 814.39. Thus, the Mitchells argue that state tort law that would require those changes is consistent with the MDA and not preempted. This argument fails to observe the distinction between allowing an act and requiring that act. The MDA allows, but does not require, the manufacturer to change its label.[20] Requiring the manufacturer to do so via a failure to warn claim would impose an additional requirement with

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[20] The Mitchells cite 21 C.F.R. § 201.57(e) as authority requiring Collagen to add a warning to product labeling as soon as evidence of an association with a serious hazard exists. The cited regulation applies to drugs, not products, although the Mitchells' attorneys represent otherwise in quoting it by deleting a reference to drug and replacing it with "[product]." Plaintiffs' Brief contains a disturbing number of similar examples of misleading quotations.

respect to safety, and such a tort is therefore preempted by the MDA. *Stamps*, 984 F.2d at 1424.

Finally, the Mitchells assert that their claims of product mislabeling, misbranding and adulteration are not preempted. In the court's view the Mitchells admit that these claims are the same as their claims of fraud and misrepresentation in product labeling (i.e., the products are misbranded or mislabeled because they were not safe and effective when used in accordance with their labeling), Plaintiffs' Brief, p. 13, and, as explained above, such claims are preempted. *King*, 983 F.2d at 1136.

To the extent that the Mitchells' claim is that the products were adulterated, *i.e.*, were not the products approved by the FDA as described in Collagen's PMA application, the Mitchells, as with their claims of fraud in the application for premarket approval, have simply rested on their pleadings. Thus, these claims, even if not preempted, fail because the Mitchells have pointed to no evidence of adulteration upon which they could go to a jury.

Because plaintiff Barbara Mitchell's claims are decided against her on the merits, the derivative claim of her spouse, plaintiff Gregory Mitchell, for loss of consortium, is not viable. *Board of Commissioners of Cass County v. Nevitt*, 448 N.E.2d 333, 341 (Ind. Ct. App. 1983). Collagen is therefore entitled to summary judgment thereon.

CONCLUSION

As explained in this overly-lengthy order and memorandum opinion, the court DENIES the Mitchells'

motions to amend their complaint. The court finds that the state common law tort causes of action pleaded by the Mitchells are either unsupported by any evidence creating an issue of fact upon which the issue could be submitted to a jury, or are preempted by the MDA. As a result, Collagen's motion for summary judgment is GRANTED. The clerk shall enter a final judgment in favor of defendant Collagen Corporation, plaintiffs Barbara and Gregory Mitchell to take nothing by their action. Costs of action as allowed by RULE 54(d).

SO ORDERED.

ENTER: November 7, 1994

/s/ James T. Moody
JUDGE, UNITED STATES
DISTRICT COURT

(2)

Supreme Court, U.S.
FILED
APR 11 1996

No. 95-1323

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

BARBARA MITCHELL, *et al.*,
Petitioners,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

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BRIEF IN RESPONSE TO THE PETITION

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QUESTIONS PRESENTED

1. Whether 21 U.S.C. § 360k(a) preempts common law claims challenging the safety or effectiveness of a medical device that the Food and Drug Administration has found to be safe and effective and has approved for marketing pursuant to the premarket approval process under 21 U.S.C. § 360e(c).

2. Whether petitioners adduced sufficient evidence to establish genuine issues of material fact respecting claims of fraud and breach of express warranty.*

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* Respondent Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

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BRIEF IN RESPONSE TO THE PETITION

STATEMENT

1. Company history and regulatory background.

In the early 1970s, a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized petitioner Collagen Corporation to manufacture and distribute collagen products to be used in various medical treatments. The principal product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to

regulation under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360*l*. "Class III devices must generally undergo premarket approval (PMA) before the FDA will allow them into the marketplace." *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1339 (11th Cir. 1995), *cert. granted*, 116 S.Ct. 806 (January 19, 1996) (Nos. 95-754 and 95-886). The premarket approval process under 21 U.S.C. § 360e(c) (the "PMA process") is central to the statutory objective of ensuring that all medical devices on the market afford "reasonable assurance of safety and effectiveness." 21 U.S.C. § 360c(1)(c). Before the FDA approves a Class III device for marketing pursuant to the PMA process, it determines that the device is safe and effective with respect to (1) the persons for whose use the device is intended and (2) the conditions of use prescribed, recommended, or suggested in the labeling of the device. 21 U.S.C. § 360c(2).

The PMA process is not the exclusive means by which Class III medical devices enter the market. The MDA provides three alternative routes to marketability: premarket approval is not required for (1) devices on the market prior to the effective date of the MDA, (2) devices found to be substantially equivalent to a device already on the market, or (3) devices entitled to the investigational device exemption. *See* 21 U.S.C. §§ 360e(b)(1)(A) and (B), 360j(g). But premarket approval is the statutory paradigm, and "the MDA contemplates that most Class III devices will reach the market through the PMA process." *Lohr*, 56 F.3d at 1340; *see* 21 U.S.C. § 360e(a).

The PMA process entails an exhaustive investigation into safety and effectiveness. An applicant who seeks the FDA's approval to market a Class III device must provide:

> (A) full reports of all information, published or known to . . . the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture [and] processing . . . of such device;

(D) . . . adequate information to show that . . . such device fully meets [pertinent] performance standard[s] . . .;

(E) . . . samples of such device . . .;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information . . . as the [FDA] . . . may require.

21 U.S.C. § 360e(c)(1).

The application for premarket approval also must include, *inter alia*, a "general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended," an "explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device," and a "description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended." 21 C.F.R. § 814.20(b)(3). The application must be periodically updated "with new safety and effectiveness information learned about the device from ongoing or completed studies." 21 C.F.R. § 814.20(e).

A completed application is reviewed by a panel of experts. 21 U.S.C. § 360e(c)(2). After considering the panel's report and recommendation, the FDA will grant the application only if it finds reasonable assurance (1) that the device is safe and effective with respect to both the persons for whose use the device is intended and the

conditions of use prescribed, recommended, or suggested in its labeling, (2) that the manufacturing and processing method and facilities are satisfactory, and (3) that the proposed labeling is not false or misleading in any manner. 21 U.S.C. §§ 360c(2) and 360e(d)(2); *see also* 21 C.F.R. § 814.44.

Collagen filed an application with the FDA for premarket approval of Zyderm on April 30, 1980. Its application included, *inter alia,* the results of clinical testing in over five thousand human subjects. Erickson Aff., Ex. 2 ("Erickson Aff." refers to an affidavit submitted by Collagen in support of summary judgment). Following more than one year of detailed investigation, the FDA found Zyderm to be safe and effective and approved it for marketing. 46 Fed. Reg. 46394 (1981). The FDA's approval order for Zyderm set forth numerous "conditions of approval," including the following:

> *Before making any change that may affect the safety or effectiveness* of the device, [Collagen must] submit a supplemental PMA for review and approval by FDA. Such changes include, but are not limited to:
>
> (1) new indications for use;
>
> (2) labeling changes;
>
> (3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;
>
> (4) changes in sterilization procedures;
>
> (5) changes in packaging;
>
> (6) changes in the performance or design specifications, circuits, parts, components, accessories, ingredients, or physical layout of the device.

Erickson Aff., Ex. 10 (emphasis in original). In 1985, the FDA issued a similar approval order, with similar conditions, for the marketing of Zyplast® Collagen Implant ("Zyplast"), a form of Zyderm that is cross-linked with glutaraldehyde. *Id.*, Ex. 36.

Collagen has marketed Zyderm since 1981, and Zyplast since 1985, as prescription-only medical devices, strictly in accordance with the conditions and other requirements imposed by the FDA. During this time, and as required by regulation, Collagen has furnished the FDA with information about "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device" and "[r]eports in the scientific literature concerning the device." 21 C.F.R. § 818.84(b)(2). In 1991, after ten years of clinical experience, the FDA undertook a review of the record of Zyderm's performance. Erickson Aff. at 5. At the conclusion of that review, the FDA reaffirmed its finding of safety and effectiveness. *Id.*

2. Proceedings in this case.

In 1988, petitioner Barbara Mitchell received a series of injections of Zyderm and Zyplast as treatment for facial wrinkles. She claims that subsequent to her treatment she developed an autoimmune disease and that Zyderm or Zyplast caused this disease. In 1993, she and her husband brought suit against Collagen in an Indiana state court, alleging negligence, strict liability, mislabeling and adulteration, fraud, and breach of warranty. Collagen removed the case to the United States District Court for the Northern District of Indiana, where jurisdiction rested on 28 U.S.C. § 1332.

The district court granted summary judgment for Collagen on the ground that petitioners' tort claims were precluded by the MDA preemption statute, 21 U.S.C. § 360k (a). That statute bars the states from imposing, with respect to a medical device, "any requirement—(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." The district court determined, following *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992),

that (1) state tort law imposes "requirements" within the meaning of the MDA preemption statute and (2) that enforcement of the particular tort laws invoked by petitioners would result in the imposition of state requirements different from or in addition to the federal requirements applicable to Zyderm under the MDA. Pet. App. 45-69.

The Seventh Circuit affirmed. Drawing support from the reasoning of a majority of the Justices in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the court first determined that "[t]he phrase 'any requirement' in 21 U.S.C. §360k(a) is broad enough to include at least some common law causes of action within the statute's preemptive scope." Pet. App. 13. The court observed, moreover, that its holding in this regard was consistent with that of "every circuit that has considered the question." *Id.* at 12 and n.3 (citing decisions from the First, Third, Fifth, Eighth, Ninth, and Eleventh Circuits).

In reaching this conclusion, the Seventh Circuit rejected the Mitchells' contention that an FDA regulation, 21 C.F.R. § 808.1(d), exempts state common law from preemption. That regulation construes the MDA preemption statute as "not preempt[ing] State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices . . . ." Expressly agreeing with the decision of the Third Circuit in *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994), the court explained:

> the regulation does not speak to common law claims; its reference to requirements of "general applicability" is not to common law causes of action but to electrical codes and the U.C.C.—positive enactments of law. Indeed, section 808.1(d), listing various state requirements that are not preempted by the statute, is noticeably silent on the matter of state tort claims when read in its entirety . . . . [I]f we were to give

> 21 C.F.R. § 808.1(d) the breadth which the Mitchells urge that we give it, we would contradict squarely the manifest intent of the statute which, as we have already noted, clearly evidences a congressional intent to preempt [at least] some common law causes of action.

Pet. App. 16.

The Seventh Circuit next turned to the Mitchells' contention that Zyderm is not subject to any federal "requirement" within the meaning of the MDA preemption statute. The Mitchells relied upon another paragraph of 21 C.F.R. § 808.1(d), providing that "state or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." Expressly agreeing with the reasoning of the Eleventh Circuit in *Lohr*, the court "conclude[d] that the premarket approval process constitutes a 'specific requirement' for purposes of 21 C.F.R. § 808.1(d)." Pet. App. 20; *see also id.* at n.6 (pointing out that, in addition, the First, Third, Fifth, and Eighth Circuits also have reached the same conclusion).

The Seventh Circuit then proceeded to "analyze each of the Mitchells' claims against Collagen to determine whether they would add requirements 'different from, or in addition to,' the PMA process or other FDA requirements and therefore be preempted." Pet. App. 21-22. Turning first to the Mitchells' negligence and strict liability claims, the court "agree[d] with several other circuits which have considered the issue that, with respect to a Class III device that has undergone the PMA process, such claims are preempted because they undoubtedly would add requirements 'different from, or in addition to,' those set forth in the MDA." *Id.* at 23 and n.7 (citing cases).

With respect to the Mitchells' claim of mislabeling and adulteration, the Seventh Circuit held that "[t]o the extent this allegation charges that Zyderm, despite con-

formity to the FDA's premarket approval process, was mislabeled, misbranded, or adulterated, the . . . claim would be preempted for the [same] reasons." Pet. App. 25. On the other hand, even if the adulteration claim could be viewed as alleging that "Collagen [had] failed to meet the labeling and purity standards established *by* the PMA process," *id.* at 26 (emphasis in original), summary judgment was proper because Collagen demonstrated in the district court "not only that adulteration claims should be preempted per se, but also that no geninue issue of material fact existed with respect to the Mitchells' adulteration claim." *Id.* at 29.

The Mitchells asserted two distinct claims of fraud and misrepresentation: that Collagen had defrauded the FDA during the PMA process, and that Collagen had committed fraud in the course of marketing Zyderm. As to the Mitchells' "fraud on the FDA" theory, the Seventh Circuit agreed with the First Circuit in *Talbott v. C. R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, Feb. 16, 1996 (No. 95-1321), and the Third Circuit in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995), that the MDA preemption statute "does not permit such a searching state inquiry into the inner workings of FDA procedures." Pet. App. 31. As to the claim of marketing fraud, the court noted that the Mitchells appeared to be contending that the FDA had approved fraudulent packaging and labeling; such a contention, the court held, was clearly preempted. *Id.* at 31. But even if, "giv[ing] the Mitchells the benefit of the doubt," *id.* at 32, their claims were construed as alleging that Collagen had departed from its FDA-approved packaging and labeling, summary judgment was proper: Collagen had introduced evidence showing that its advertising and promotional materials conformed to the FDA's requirements, and "[t]he Mitchells did not introduce affidavits, depositions, or other materials either to rebut Collagen's submissions or to demonstrate that there were genuine issues with respect to other promotional materials." *Id.* at 33.

The Mitchells had made a general allegation of breach of warranty without "specif[ying] what warranties were at issue nor what statements of warranty Collagen allegedly provided." Pet. App. 33-34. The Seventh Circuit agreed with the First, Third, Fifth, Eighth, and Eleventh Circuits that all claims of implied warranty are preempted. *Id.* at 34-35 and n.11. At the same time, the court agreed with the Third Circuit (and disagreed with the First Circuit) in holding that claims of express warranty are not preempted. *Id.* at 35-37. The court concluded, however, that "the Mitchells' summary judgment filings prevent them from benefitting from this analysis." *Id.* at 37. The court explained:

> the Mitchells never specified in the district court whether their claim was based upon implied or express warranties. Likewise, the Mitchells never pointed to any express warranty that Collagen allegedly violated. In response to Collagen's submission that there was no genuine issue of material fact with respect to their complaint against Collagen, the Mitchells introduced no affidavits, depositions, documents, or other evidence creating a genuine issue of fact as to the existence of any express warranty provided by Collagen. Accordingly, we must hold that the Mitchells failed to meet their burden at the summary judgment stage . . . .

Pet. App. 38.

DISCUSSION

This case involves three important issues concerning the application of the MDA preemption statute to Class III medical devices that the FDA has found to be safe and effective and has approved for marketing pursuant to the rigorous and comprehensive PMA process. The circuits are split over each of these issues, and the resulting conflicts should be resolved.

(1) The Seventh Circuit in this case, like the First, Second, Third, Fourth, Fifth, Sixth, Eighth, and Eleventh Circuits in other cases, holds that state common law

imposes "requirements" within the meaning of the MDA preemption statute and thus is subject to preemption. *See, e.g., Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994); *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2d Cir. 1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 397-98 (4th Cir. 1995); *Reeves v. Acromed Corp.*, 44 F.3d 300, 304 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); *Martin v. Telectronics Pacing Systems, Inc.*, 70 F.3d 39, 41 (6th Cir. 1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 991 (8th Cir. 1994); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (January 19, 1996) (Nos. 95-754 and 95-886). The Ninth Circuit, however, has held that state common law does not impose "requirements" and thus falls outside the scope of the MDA preemption statute. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1460-61 (9th Cir. 1995). Collagen intends to file a petition for writ of certiorari in *Kennedy*, but this Court presumably will resolve the conflict in *Medtronic*.

(2) The Seventh Circuit in this case, like the First, Third, Fifth, and Eighth Circuits in other cases, holds that the requirements imposed by the FDA in connection with the PMA process also are "requirements" within the meaning of the MDA preemption statute and thus give rise to preemption. *See, e.g., King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir), *cert. denied*, 116 S. Ct. 67 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-22 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Martello v. Ciba Vision Corp.*, 43 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995). On the other hand, the Ninth Circuit in *Kennedy* held that the PMA process itself is not a "requirement" under the MDA preemption statute and, in addi-

tion, appeared to believe that the PMA process does not impose any "requirements" either. *See* 67 F.3d at 1459-60. This issue is not directly before the Court in *Medtronic,* which involves a medical device granted premarket clearance by the FDA pursuant to the more abbreviated notification procedure under 21 U.S.C. § 360 (k) (the "510(k) process"). If this Court in *Medtronic* concludes, however, that the 510(k) process imposes "requirements," then the same result for the PMA process follows *a fortiori.* But if the Court does not reach that issue or that conclusion in *Medtronic,* the existing conflict with respect to the PMA process will remain. This conflict could appropriately be resolved either in *Kennedy* or in this case.

(3) The Seventh Circuit in this case, like the Third Circuit in *Michael,* 43 F.3d at 1325, holds that claims based on a common law theory of express warranty are not barred by the MDA preemption statute. The First and Sixth Circuits hold, to the contrary, that express warranty claims are preempted. *Talbott v. C. R. Bard, Inc.,* 63 F.3d 25, 29 (1st Cir. 1995), *petition for cert. filed,* Feb. 16, 1996 (No. 95-1321); *Martin,* 70 F.3d at 42. The Fourth Circuit holds that express warranty claims are preempted to the extent that they are based on FDA-mandated labeling, packaging, or advertising but are not preempted otherwise. *Duvall,* 65 F.3d at 400. This issue is not presented in *Medtronic,* and the existing conflict therefore will survive the decision in that case. Because the Seventh Circuit ruled against the Mitchells' express warranty claim on another ground, however, the MDA preemption statute provides only an alternative basis for affirming that ruling; this Court thus might not have occasion to reach the preemption issue in this case. *Kennedy* provides a better vehicle for deciding this issue.

I. WITH THE EXCEPTION OF ITS ANALYSIS OF EXPRESS WARRANTY CLAIMS, THE DECISION BELOW IS CORRECT WITH RESPECT TO PREEMPTION UNDER THE MDA.

a. The Seventh Circuit correctly held that "[t]he phrase 'any requirement' in 21 U.S.C. § 360k(a) is broad enough to include at least some common law causes of action within the statute's preemptive scope." Pet. App. 13. This issue has been fully briefed to the Court in *Medtronic*, and for the present Collagen simply adopts the reasoning of the court below and that of Medtronic and its supporting *amici curiae* with respect to that issue.

b. The detailed and demanding PMA process both encompasses and imposes requirements giving rise to preemption under the MDA preemption statute. In arguing the contrary, the Mitchells rely upon 21 C.F.R. § 808.1 (d), which provides that "state or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." This reliance is doubly misplaced. The FDA itself has explained that for Class III medical devices like Zyderm "the counterpart FDA requirement [is] the requirement that the product have premarket approval." 43 Fed. Reg. 18661, 18664 (1978). Beyond that, and as the facts of this case demonstrate, the marketing approval order generated by the PMA process imposes numerous "specific requirements applicable to [the] particular device." *See* p. 4, *supra*. The Seventh Circuit plainly was correct in holding that Zyderm is subject to federal "requirements" within the meaning of the MDA preemption statute.

c. Claims based upon theories of strict liability, negligence, mislabeling, misbranding, adulteration, fraud, misrepresentation, and implied warranty all, at bottom, are claims that the medical device should have been designed, manufactured, packaged, labeled, and advertised in a

manner different from that both explicitly approved by the FDA upon finding the device safe and effective and explicitly required by the FDA as a condition of continued marketability. The central purpose of the MDA preemption statute is to protect manufacturers of medical devices from conflicting demands of this sort. With the exception of the Ninth Circuit's aberrant decision in *Kennedy*, every circuit that has reached this issue has so held. The decision of the Seventh Circuit on this issue was, once again, plainly correct.

d. The Seventh Circuit erred, however, in holding that the Mitchells' express warranty claim (if, indeed, the claim can be so characterized) is not preempted. The Mitchells alleged, with no elaboration or supporting evidence, that Collagen had "warranted and represented . . . that [Zyderm was] safe for [its] intended use and purpose." Pet. App. 33. To prevail on the merits of that claim, the Mitchells would have to persuade a court or jury to find, *inter alia*, that Zyderm is not safe. Such a finding would directly contradict the FDA's explicit determination that Zyderm is safe and effective. Positing liability on that ground, moreover, would impose a state-law based requirement that Collagen change its manufacturing or other processes so as to make Zyderm "safe" by state-law standards. It would, in other words, impose state requirements different from, or in addition to, the federal requirements imposed under the MDA. That result is expressly prohibited by the MDA preemption statute.

II. THE JUDGMENT BELOW WAS CORRECT.

The Seventh Circuit correctly determined that the Mitchells had not adduced sufficient evidence relating to their claims of fraud and express warranty to survive summary judgment. The Mitchells contest that holding, which of course was rooted in the particular summary judgment record of this case. But the Mitchells' contentions are insubstantial, and the narrow record-based issues

that they seek to raise do not, in any event, warrant review by this Court.

With respect to the allegation of fraud, it is apparent that the Mitchells sought to change the character and purported factual basis of their fraud claim on appeal, shifting their attack from Collagen's packaging and labeling to its advertising and promotional materials. *See* Pet. App. 31-32. But in moving for summary judgment in the district court, Collagen had demonstrated that its advertising and promotional materials, as well as its packaging and labeling, were subject to federal constraints and were in compliance with federal requirements. *Id.* at 33 and n.10. The Mitchells made no effort to rebut this showing. The Seventh Circuit correctly held that, on this record, the Mitchells' fraud claim was preempted.

The Mitchells' express warranty claim also was an apparent afterthought, asserted for the first time on appeal. *See* Pet. App. 38. The Seventh Circuit understandably was of the view that because the Mitchells had failed to specify or support such a claim in the district court in response to Collagen's submission that their complaint raised no genuine issues of material fact, "summary judgment was proper even though [in the court's view] such [express warranty] claims are not preempted by the MDA." *Id.* This holding does not warrant further review. Furthermore, as Collagen argued below, to the extent that the Mitchells' claim can be construed as alleging a breach of express warranty, it is barred by state law on two separate grounds: (1) there was no privity of contract between Collagen and the Mitchells, as required by Indiana law, *see, e.g., DeHoyos v. John Mohr & Sons,* 629 F. Supp. 69, 80 (N.D. Ind. 1984), *aff'd sub nom. Black v. Henry Pratt Co.,* 778 F.2d 1278 (7th Cir. 1985); (2) the Mitchells' action was not begun within the four-year Indiana statute of limitations for express warranty claims, *see Ferdinand Furniture Co. v. Anderson,* 399 N.E.2d 799, 802 (Ind. App. 1980).

CONCLUSION

The petition should be held pending disposition first of *Medtronic* and then of *Kennedy*; it should then be granted if, and only to the extent that, it presents preemption issues left unresolved by this Court's disposition of those cases.

Respectfully submitted,

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